Package leaflet: Information for the user

Paingone 200 mg tablets

ibuprofen

Read this entire package leaflet carefully before you start using this medicine as it contains important information for you.

- Use this medicine exactly as described in this package leaflet or as your doctor or pharmacist has advised you.
- Keep this package leaflet. You may need to read it again.
- If you have any further questions or require advice, ask your pharmacist.
- If you notice any adverse reactions, tell your doctor or pharmacist. This also applies to any adverse reactions not listed in this leaflet.
- Consult your doctor if your condition does not improve after a few days, or it takes a turn for the worse.

This leaflet explains:

1. What is Paingone and what is it used for
2. What must you know before taking Paingone tablets
3. How Paingone tablets are used
4. Possible adverse reactions
5. How to store Paingone tablets
6. Package contents and further information

1. What is Paingone and what is it used for

The ibuprofen contained in Paingone tablets is a so-called anti-inflammatory analgesic. Ibuprofen reduces substances that cause pain and inflammation in the system, alleviating pain, reducing redness, warmth and swelling, and it lowers fever.

Indications

Paingone tablets are used temporarily for the treatment of pain and fever, such as flu symptoms, muscle and joint pain, headache, menstrual pain, arthritis pain or toothache.

Your doctor might have prescribed you Paingone tablets for treating some other disease not mentioned above.

2. What must you know before taking Paingone tablets

Do not use Paingone tablets:

- if you are allergic to ibuprofen or some other anti-inflammatory drug, or other ingredients of the Paingone tablets (see Section 6 of the package leaflet)
- if you have or have had peptic ulcer or duodenal ulcer
- if you have severe cardiac insufficiency (causes shortness of breath and swelling)
- if you have asthma and you are allergic (hypersensitive) to acetyl salicylic acid or some other anti-inflammatory drug
- if you are in the last trimester of pregnancy

Warnings and precautions

Do not exceed the recommended duration of treatment. Only for temporary and short-term use without a doctor's prescription.

Consult your doctor or pharmacist before starting to take Paingone tablets, if:

- you have renal or hepatic insufficiency
- if you have ulcerative colitis (Colitis ulcerosa) or Crohn's disease
- if you have asthma

Also tell your doctor if you have other diseases or allergies.

Children and teenagers suffering from fluid loss face a danger for renal insufficiency.

Other medicinal products and Paingone

Please tell your doctor or pharmacist about all medicines you are taking. This applies to both prescription medicines and over-the-counter medicines, herbal remedies, and natural products. Also remember to mention if you have recently taken some medicine. The effect of some medicines may change, or they may change the effect of Paingone tablets if they are taken at the same time. In such a case, your doctor may alter your medication or the dosage instruction.

Examples of such pharmaceutical products include

- Other anti-inflammatory drugs must not be used simultaneously with Paingone, as only the adverse effects would increase, not the efficacy blood-thinning or anticoagulant medicines
- antihypertensive medicines (their effect might be reduced)
- orally taken cortisone tablets (the risk of peptic ulcer or duodenal ulcer increases)

Always consult your doctor or pharmacist before you use Paingone simultaneously with other medicines.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, or you suspect you are pregnant, consult your doctor or pharmacist before using this medicine.

Driving and using machines

Paingone does not usually have any detrimental effect on alertness or performance. For some patients, Paingone may cause drowsiness or other adverse effects that reduce performance (see Section 4 of the package leaflet). If this is the case with you, you should avoid driving and other tasks that require alertness.

3. How Paingone tablets are used

Take the tablets with a sufficient amount of fluid (for example, a glass of water).

Eating does not affect the efficacy of the medicine.

If a child or teenager needs this medicine for longer than 3 days, or if his/her symptoms worsen, contact a doctor.

Long-term use is allowed only on the order of a doctor.

Adults and children over 12 years of age:
1-2 tablets, a maximum of 1–3 times a day.

Children:
For children, the maximum single dose is 10 mg/kg, and the maximum daily dose is 30 mg/kg.

Age	Weight	Dose
1–2 years	10–14 kg	One half tablet up to 2 times a day
2–4 years	14–20 kg	One half tablet up to 3 times a day
4–8 years	20–25 kg	1 tablet up to three times a day
8–12 years	25–40 kg	1 tablet up to four times a day.

Paingone 200 mg tablets are not suitable for the treatment of children weighing less than 10 kg. There are other forms of the product available for them.

If you take more Paingone tablets than you should

If you have taken a dose that is too high, or your child has accidentally taken the medicine, always contact your doctor, a hospital, or the Poison Information Centre (tel. +358 800 147 111) for a risk assessment and further instructions.

If you have any questions about the use of this medicine, please consult your doctor or pharmacist.

4. Possible adverse reactions

Like all medicines, Paingone can cause adverse reactions, although not everybody gets them.

Patients in poor condition with multiple illnesses and elderly patients have more adverse reactions. The risk of serious adverse effects is increased with high dosages in long-term use and are multiplied if other anti-inflammatory analgesics are used at the same time.

Common adverse reactions (more than 1 patient out of one hundred):
- low spirits or drowsiness
- dizziness or headache
- heartburn, upper stomach pain, nausea, or diarrhoea
- urticaria, itching of the skin, or swelling of the mucous membranes
- ringing in the ears
- worsening of cardiac insufficiency

Uncommon adverse reactions (fewer than 1 patient out of one hundred):
- nervousness, nightmares
- ulcers and bleeding in the digestive tract
- sensations of pins and needles in the skin

Rare adverse reactions (fewer than 1 patient out of one thousand):
- dimming of vision
- scaly or blistering skin reactions
- strong allergic symptoms
- impairment of renal function

Stop using the medicine and **immediately** contact a doctor or the nearest emergency clinic if the following symptoms appear:
- breathing difficulties or dyspnoea

- strong skin erythema, itching, swelling
- swelling of the tongue and throat
- sudden, hard stomach pain or vomiting of blood

Contact a doctor **as soon as possible**, if you have any of the following symptoms:
- heartburn and milder stomach ailments
- black stools
- increased tendency for bruising or nosebleed
- swelling of the extremities
- other cutaneous symptoms

Reporting adverse reactions

If you notice any adverse reactions, tell your doctor or pharmacist. This also applies to all adverse reactions not listed in this leaflet. You can also report adverse reactions directly (please see the contact information below). By reporting adverse reactions, you can help in increasing our awareness of the safety of this medicinal product.

website: www.fimea.fi
Finnish Medicines Agency Fimea
Adverse drug reaction database
PL 55
FI-00034 Fimea

5. How to store Paingone tablets

Keep out of the sight and reach of children.

This medicine does not require special storage conditions.

Do not use this medicine after the expiry date stated on the package (Use. last. or EXP). The expiry date means the last day of the month.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Package contents and further information

What Paingone tablets contain

The active substance is ibuprofen. One tablet contains 200 mg of ibuprofen.

The other ingredients are lactose monohydrate, microcrystalline cellulose, pregelatinised starch, croscarmellose sodium, and magnesium stearate.

Description of the medicinal product and package sizes

Paingone 200 mg is a white, round and biconvex film-coated tablet with a diameter of 8.2 mm.

Package sizes: 20, 30, or 50 tablets in a blister package.

All package sizes are not necessarily for sale.

Marketing authorisation holder and manufacturer

Medicine Factory Ltd
Tablet Road 1
12345 Medville
Finland

This leaflet was last approved on

14.12.2021

This package leaflet was adapted from the leaflets of products containing ibuprofen. Actual package leaflets are more extensive and detailed

Package leaflet: Information for the user

Sneezix 10 mg tablets

cetirizine

Read this entire package leaflet carefully before you start using this medicine as it contains important information for you.
- Use this medicine exactly as described in this package leaflet.
- Keep this package leaflet. You may need to read it again.
- If you have any further questions or require advice, ask your pharmacist.
- Please contact a doctor if your symptoms worsen or are not alleviated within 3 days
- If you notice any adverse reactions, tell your doctor or pharmacist. This also applies to any adverse reactions not listed in this leaflet.

In this leaflet:

1. What is Sneezix and what is it used for
2. What must you know before taking Sneezix tablets
3. How Sneezix tablets are used
4. Possible adverse reactions
5. How to store Sneezix tablets
6. Package contents and further information

1. What is Sneezix and what is it used for

The active substance of Sneezix is cetirizine. Sneezix is an allergy medicine.

Cetirizine is used for treating allergic symptoms in adults and in children of at least 6 years of age. These symptoms include:
- allergic rhinitis (congested or runny nose, itching, and sneezing),
- allergic eye symptoms (redness, watering, and itching of the eyes),
- allergic urticaria

2. What must you know before taking Sneezix tablets

Do not use Sneezix tablets:
- if you are allergic to cetirizine or other ingredients of the Sneezix tablets (see Section 6 of the package leaflet)
- if you are sensitive to hydroxyzine or piperazine derivatives (substances related to the active substance in this medicinal product)
- if you have severe renal insufficiency

Warnings and precautions

Consult with your doctor or pharmacist before you take Sneezix:
- if you have renal insufficiency
- if you have epilepsy or are prone to convulsions,
- if you are going to an allergy test, do not take this medicine for three days prior to the test

<u>Children</u>

Do not give this medicine to a child less than 6 years of age, since the tablet form precludes the necessary changes to the dose.

Other medicinal products and Sneezix

Tell your doctor or pharmacist if you are using or have used or might use other medicinal products.

Pregnancy and breast-feeding

Sneezix should be avoided during pregnancy.

Driving and using machines

Clinical studies have not shown any impairment of alertness, alertness or ability to drive when used at the recommended doses.

Keep a close eye on how your body reacts to the Sneezix tablet you take if you are going to drive, take any dangerous action or use machines.

3. How Sneezix tablets are used

Take the tablets with a sufficient amount of fluid (for example, a glass of water).

Adults and children over 12 years of age:
1 tablet once a day.

Children 6–12 years old:
Half a tablet 1–2 times a day.

Duration of treatment

The duration of treatment depends on the nature, duration and progress of your symptoms. Your doctor determines the length of treatment.

If you take more Sneezix tablets than you should

If you have taken a dose that is too high, or your child has accidentally taken the medicine, always contact your doctor, a hospital, or the Poison Information Centre (tel. +358 800 147 111) for a risk assessment and further instructions.

After an overdose, the following adverse reactions might occur stronger than usual: confusion, diarrhoea, dizziness, tiredness, headache, poor general condition, mydriasis, itching, restlessness, tranquilising effect of the medicine, drowsiness, grogginess, abnormally fast heart rate, tremor and urinary retention.

4. Possible adverse reactions

Like all medicines, Sneezix can cause adverse reactions, although not everybody gets them.

Common adverse reactions (may occur in 1 in 10 patients):
- drowsiness or exhaustion
- dizziness or headache
- diarrhoea, nausea, dry mouth

Uncommon adverse reactions (may occur in 1 in 100 patients):
- restlessness
- stomach ache

- weakness

Rare adverse reactions (may occur in 1 in 100 patients):
- low spirits or sleeplessness
- convulsions
- rapid heartbeat
- swelling

Reporting adverse reactions

If you notice any adverse reactions, tell your doctor or pharmacist. This also applies to all adverse reactions not listed in this leaflet. You can also report adverse reactions directly (please see the contact information below). By reporting adverse reactions, you can help in increasing our awareness of the safety of this medicinal product.

website: www.fimea.fi
Finnish Medicines Agency Fimea
Adverse drug reaction database
PL 55
FI-00034 FIMEA, Finland

5. How to store Sneezix tablets

Keep out of the sight and reach of children.

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date stated on the package (Use by or EXP). The expiry date means the last day of the month.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Package contents and further information

What Sneezix tablets contain

The active substance is cetirizine. One tablet contains 10 mg of cetirizine.The other ingredients are lactose monohydrate, microcrystalline cellulose, maize starch, and magnesium stearate.

Description of the medicinal product and package sizes

Sneezix 10 mg is a white or near-white, oval and biconvex tablet, the length of which is around 8 mm.

There is a splitting groove on one side of the tablet.

Package sizes: 10 or 30 tablets in a blister package.

All package sizes are not necessarily for sale.

Marketing authorisation holder and manufacturer

Medicine Factory Ltd
Tablet Road 1

12345 Medville
Finland

This leaflet was last approved on

14.12.2021

This package leaflet was adapted from the leaflets of products containing cetirizine. Actual package leaflets are more extensive and detailed.

Package leaflet: Information for the user

Acheaway 500 mg tablets

paracetamol

Read all of this package leaflet carefully before you start taking this medicine as it contains important information for you.

- Use this medicine exactly as described in this package leaflet or as your doctor or pharmacist has advised you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions or require advice, ask your pharmacist.
- If you notice any adverse reactions, tell your doctor or pharmacist. This also applies to any adverse reactions not listed in this leaflet.
- Consult your doctor if your condition does not improve after 3 to 4 days, or it takes a turn for the worse.

In this leaflet:

1. What is Acheaway and what is it used for
2. What must you know before taking Acheaway tablets
3. How Acheaway tablets are used
4. Possible adverse reactions
5. How to store Acheaway tablets
6. Package contents and further information

1. What is Acheaway and what is it used for

Acheaway is an analgesic and antipyretic that relieves pain and reduces fever.

The Acheaway tablets are used temporarily for pain and fever. Such pains and fevers include neuralgia and muscle ache, headache, common cold, influenza, menstrual pain or toothache.

Consult a doctor if, after three days, you do not feel better or you feel worse.

2. What must you know before taking Acheaway tablets

Do not use Acheaway tablets:

- if you are allergic to paracetamol or other ingredients of the Acheaway tablets (see Section 6 of the package leaflet)
- if you have a serious liver disease and hepatic insufficiency

Warnings and precautions

Consult your doctor before beginning to take Acheaway tablets, if:

- you use alcohol
- you have a kidney disease or a liver disease
- you are underweight or underfed

Excessive use of paracetamol might seriously harm the liver. Do not exceed the recommended duration of treatment. Only for temporary and shortterm use without a doctor's prescription.

Other medicinal products and Acheaway

Please tell your doctor or pharmacist about all medicines you are taking. This applies to both prescription medicines and over-the-counter medicines, herbal remedies, and natural products. Also remember to mention if you have recently taken some medicine. The effect of some medicines may change or they may change the effect of Acheaway tablets if they are taken at the same time.

In particular, pay attention to the following kinds of medicinal products:

- the gout medicine probenecid may increase the concentration and effect of paracetamol
- epilepsy medicines (phenytoin and carbamazepine) may decrease the effect of paracetamol

Do not take other medicines that contain paracetamol at the same time.

Pregnancy and breast-feeding

The use of Acheaway tablets is allowed during pregnancy and breast-feeding. Use the lowest possible does for a short time and as rarely as possible.

Driving and using machines

Acheaway does not usually have any detrimental effect on alertness or performance.

3. How Acheaway tablets are used

Use this medicine exactly as prescribed by your doctor. If you are unsure, check the instructions from your doctor or pharmacist.

Take the tablets with a sufficient amount of fluid (for example, a glass of water).

Adults:
1-2 tablets up to three times a day.

Children over 6 years of age:
For children, the maximum single dose is 15 mg/kg, and the maximum daily dose is 45 mg/kg.

Weight	Dose
17–25 kg	½ tablet up to 3 times a day
25–32 kg	½–1 tablet up to 3 times a day
yli 32 kg	1 tablet up to three times a day

Acheaway 500 mg tablets are not suitable for the treatment of children under 6 years of age or who weigh less than 17 kg. There are other forms of the product available for them.

If you take more Acheaway tablets than you should

An overdose might lead to a life-threatening liver damage.

If you have taken a dose that is too high, or your child has accidentally taken the medicine, always contact your doctor, a hospital, or the Poison Information Centre (tel. +358 800 147 111) for a risk assessment and further instructions.

4. Possible adverse reactions

Like all medicines, Acheaway can cause adverse reactions although not everybody gets them.

Very rare adverse reactions (less than one person out of 1,000 but more than one person out of 10,000):

- allergic skin reactions or swelling
- changes in haematological values
- hepatic dysfunction abdominal
- discomfort

Reporting adverse reactions

If you notice any adverse reactions, tell your doctor or pharmacist. This also applies to all adverse reactions not listed in this leaflet. Ilmoittamalla haittavaikutuksista voit auttaa saamaan enemmän tietoa tämän lääkevalmisteen turvallisuudesta.

website: www.fimea.fi
Lääkealan turvallisuus- ja kehittämiskeskus Fimea
Lääkkeiden haittavaikutusrekisteri
PL 55
00034 FIMEA

5. How to store Acheaway tablets

Keep out of the sight and reach of children.

Do not store above 25 °C.

Do not use this medicine after the expiry date stated on the package (Use. last. or EXP). The expiry date means the last day of the month.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Package contents and further information

What Acheaway tablets contain

The active substance is paracetamol. One tablet contains 500 mg of paracetamol

The other ingredients are povidone, lactose monohydrate, microcrystalline cellulose, maize starch, talc, and magnesium stearate.

Description of the medicinal product and package sizes

Acheaway 500 mg is a white and round tablet with a diameter of around 12 mm.

Package sizes: 10, 20, and 30 tablets in a blister package.

All package sizes are not necessarily for sale.

Marketing authorisation holder and manufacturer

Medicine Factory Ltd
Tablet Road 1
12345 Medville
Finland

This leaflet was last approved on

14.12.2021

This package leaflet was adapted from the leaflets of products containing paracetamol. Actual package leaflets are more extensive and detailed.

Package leaflet: Information for the user

Flugone 0.5 mg/ml nasal spray, solution

xylometazoline

Read this entire package leaflet carefully before you start using this medicine as it contains important information for you.

- Use this medicine exactly as described in this package leaflet or as your doctor or pharmacist has advised you.
- Keep this package leaflet. You may need to read it again.
- If you have any further questions or require advice, ask your pharmacist.
- If you notice any adverse reactions, tell your doctor or pharmacist. This also applies to any adverse reactions not listed in this leaflet.
- Consult your doctor if your condition does not improve or it takes a turn for the worse.

In this leaflet:

1. What is Flugone nasal spray and what is it used for
2. What must you know before using Flugone nasal spray
3. How Flugone nasal spray is used
4. Possible adverse reactions
5. How to store Flugone nasal spray
6. Package contents and further information

1. What is Flugone nasal spray and what is it used for

The medicine contracts the blood vessels in nasal mucous membranes, thus reducing the swelling of nasal mucous membranes and making breathing through the nose easier and reducing nasal secretions.

The effect of Flugone nasal spray begins quickly and lasts for approximately 6–10 hours.

Xylometazoline is used temporarily to relieve congestion during rhinitis and maxillary sinusitis.

Consult a doctor if, after 5 days, you do not feel better or you feel worse.

2. What must you know before using Flugone nasal spray

Do not use Flugone nasal spray:

- if you are allergic to xylometazoline or other ingredients of Flugone nasal spray (see Section 6 of the package leaflet)
- if you have glaucoma
- if you have inflammatory chronic nasal dryness
- you have recently undergone surgery in the head region that was performed via the nose or mouth

Warnings and precautions

Consult your doctor before you begin to use Flugone nasal spray, if:

- react strongly to products like adrenaline
- you have a cardiovascular disease
- you have hypertension
- you have hyperthyroidism
- you have diabetes (diabetes mellitus)

This product may be used for up to 5 days for children of less than 12 years of age. Excessive or prolonged use (more than 5 days) of the product might increase nasal congestion. If the nasal congestion continues for a long time, contact a doctor.

Other medicinal products and Flugone

Please tell your doctor or pharmacist about all medicines you are taking. This applies to both prescription medicines and over-the-counter medicines, herbal remedies, and natural products. Also remember to mention if you have recently taken some medicine. The effect of some medicines may change, or they may change the effect of Flugone nasal spray if they are taken at the same time.

In particular, pay attention to the following kinds of medicinal products:

- antidepressants (e.g. amitriptyline, doxepin, imipramine, clomipramine, or moclobemide)
- selegiline used to treat Parkinson's disease

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, or you suspect you are pregnant, consult your doctor or pharmacist before using this medicine.

Driving and using machines

Flugone does not usually have any detrimental effect on alertness or performance.

3. How Flugone nasal spray is used

Children 1-5 years old:
Use under adult supervision. 1 spray into each nostril 1 or 2 times a day is usually a sufficient dose. The medicine may not be used for more than three times a day in each nostril.

Children 6-11 years old:
Use under adult supervision. 1–2 sprays in both nostrils 2–3 times a day as necessary. The medicine may not be used for more than three times a day in each nostril.

Not for children under 1 years of age.
The Flugone 0.5 mg/ml nasal spray may not be used continuously for longer than 5 days for children on 1–11 years of age.

Instructions for use:

1. Clear your nose before using the nasal spray.
2. Remove the plastic cover from the spray nozzle. If you are using the spray bottle for the first time, spray 3–6 times in the air until the spray is even – do not aim the nozzle towards yourself. Do this also if the bottle has been unused for a long time.
3. Insert the nozzle into a nostril, and spray the desired amount of spray first in one nostril and then in the other nostril. When spraying, we recommend inhaling slightly through your nose, if possible.
4. Clean and dry the nozzle. Finally, replace the plastic cover on the nozzle.

If you take more Flugone nasal spray than you should

If you have taken a dose that is too high, or your child has accidentally taken the medicine, always contact your doctor, a hospital, or the Poison Information Centre (tel. +358 800 147 111) for a risk assessment and further instructions.

4. Possible adverse reactions

Like all medicines, Flugone can cause adverse reactions although not everybody gets them.

Common adverse reactions (might occur in 1 user out of 10):
- headache
- dryness of the nose, or an unpleasant feeling in the nose, a burning sensation
- nausea

Very rare adverse reactions (fewer than one patient in ten thousand):
- hypersensitivity reaction (rash, itching, or swelling of the skin)
- increased heartrate or heart palpitations

Reporting adverse reactions

If you notice any adverse reactions, tell your doctor or pharmacist. This also applies to any adverse reactions not listed in this package leaflet. You can also report adverse reactions directly (please see the contact information below). By reporting adverse reactions, you can help in increasing our awareness of the safety of this medicinal product.

website: www.fimea.fi
Finnish Medicines Agency Fimea
Adverse drug reaction database
PL 55
FI-00034 Fimea, Finland

5. How to store Flugone nasal spray

Keep out of the sight and reach of children.

Do not store above 25 °C.

The nasal spray does not contain preservatives and keeps for 3 weeks after opening.

Do not use this medicine after the expiry date stated on the package (Use.Last. or EXP). The expiry date means the last day of the month.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Package contents and further information

What Flugone nasal spray contains

The active substance is xylometazoline. 1 ml of the solution contains 0.5 mg of xylometazoline. 1 single dose of the Flugone 0.5 mg/ml nasal spray contains 25 microgrammes of xylometazoline.

The other ingredients are sodium chloride, disodium phosphate dihydrate, edetate disodium, glycerol, polysorbate 80, and purified water.

Description of the medicinal product and package sizes

Bright, colourless solution, 10 ml.

Marketing authorisation holder and manufacturer

Medicine Factory Ltd
Tablet Road 1
12345 Medville
Finland

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This package leaflet was adapted from the leaflets of products containing xylometazoline. Actual package leaflets are more extensive and detailed.

Package leaflet: Information for the user

Oculix 20 mg/ml eyedrops, solution

sodium cromoglicate

Read all of this package leaflet carefully before you start using this medicine as it contains important information for you.

- Use this medicine exactly as described in this package leaflet.
- Keep this package leaflet. You may need to read it again.
- If you have any further questions or require advice, ask your pharmacist.
- If you notice any adverse reactions, tell your doctor or pharmacist. This also applies to any adverse reactions not listed in this leaflet.
- Consult your doctor if your symptoms do not improve after 2 to 3 days, or they become worse.

In this leaflet:

1. What are Oculix eye drops and what they are used for
2. What must you know before using Oculix eye drops
3. How Oculix eye drops are used
4. Possible adverse reactions
5. How to store Oculix eye drops
6. Package contents and further information

1. What are Oculix eye drops and what they are used for

Sodium cromoglicate prevents the effects of histamine in the system. Oculix eye drops can be used prophylactically, but also after the onset of symptoms.

Sodium cromoglicate is used for the treatment and prevention of allergic eye symptoms, such as redness, swelling, and itching.

2. What must you know before using Oculix eye drops

Do not use Oculix eye drops:

- if you are allergic to sodium cromoglicate or other ingredients of the Oculix eye drops (see Section 6 of the package leaflet)

Warnings and precautions

The use of soft contact lenses is not recommended. If the use of contact lenses is absolutely necessary, the lenses must be removed before administering the drops and replaced only after 15 minutes or more has passed.

Other medicinal products and Oculix eye drops

Oculix eye drops are not known to have any effect on the efficacy of other medicines, and other medicines do not affect the efficacy of Oculix eye drops. Tell your doctor or pharmacist if you are using or have recently used other medicines, also medicines not prescribed by a doctor.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, or you suspect you are pregnant, consult your doctor or pharmacist before using this medicine.

Driving and using machines

These eye drops might cause local irritation that can affect your ability to drive or use machines.

Important information on the ingredients in Oculix

The Oculix eye drops contain the preservative benzalkonium chloride. which might irritate the eyes and cause colour changes to contact lenses.

3. How Oculix eye drops are used

For children under 4 years of age only on doctor's order.

Adults and children over 4 years of age:
1-2 drops in both eyes 4 times a day.

Instructions for use:

- The medicine is administered into the eyes:
- First, wash your hands and open the eye drop bottle.
- Tilt your head back or lay down on your back. Pull your lower eye lid down and look up.
- Drop one or two drops from the bottle between your eye and the lower eye lid; avoid touching the eye with the tip of the eye drop bottle.
- Blink your eyes a couple of times to spread the medicine on the surface of the eye.
- Close the eye drop bottle.

Treatment should be started before the start of pollen season, and it must be started at least when the first symptoms appear. You can use the medicine throughout the entire pollen season.

4. Possible adverse reactions

Like all medicines, Oculix can cause adverse reactions although not everybody gets them. In the beginning of treatment, temporary stinging and local irritation may occur. Hypersensitivity reactions have been reported very rarely.

Reporting adverse reactions

If you notice any adverse reactions, tell your doctor or pharmacist. This also applies to any adverse reactions not listed in this leaflet. You can also report adverse reactions directly (please see the contact information below). By reporting adverse reactions, you can help in increasing our awareness of the safety of this medicinal product.

website: www.fimea.fi
Finnish Medicines Agency Fimea
Register for adverse drug reactions
P.O. Box 55,
FI-00034 FIMEA, Finland

5. How to store Oculix eye drops

Keep out of the sight and reach of children.
Store in a temperature less than 25°C. Store the bottle in the outer package. Sensitive to light.

Do not use this medicine after the expiry date stated on the package (Last.use. or EXP). The expiry date means the last day of the month. An opened bottle keeps for 28 days. Store the bottle tightly closed.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Package contents and further information

What Oculix eye drops contain

The active substance is sodium cromoglicate. 1 ml of the solution contains 20 mg of sodium cromoglicate.

The other ingredients are benzalkonium chloride 50 microgrammes/ml, glycerol, edetate sodium, and water used for injection fluids.

Description of the medicinal product and package sizes

Clear, colourless solution in a white 10 ml plastic bottle with a white plastic twist cap.

One bottle contains around 200 drops.

Marketing authorisation holder and manufacturer

Medicine Factory Ltd
Tablet Road 1
12345 Medville
Finland

This leaflet was last approved on

14.12.2021

This package leaflet was adapted from the leaflets of products containing sodium cromoglicate. Actual package leaflets are more extensive and detailed.

Package leaflet: Information for the patient

Germaway 500 mg tablets

phenoxymethylpenicillin

Read this entire package leaflet carefully before you start using this medicine as it contains important information for you.

- Keep this package leaflet. You may need to read it again.
- If you have any questions, consult your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm others, even if their symptoms are similar to yours.
- If you notice any adverse reactions, consult your doctor or pharmacist, even if the adverse reactions you experience are not listed in this package leaflet.

In this leaflet:

1. What is Germaway and what is it used for
2. What must you know before taking Germaway tablets
3. How Germaway tablets are used
4. Possible adverse reactions
5. How to store Germaway tablets
6. Package contents and further information

1. What is Germaway and what is it used for

Penicillin is an antibiotic that is used to treat various bacterial inflammations. Germaway tablets are most commonly used to treat bacterial inflammations in the mouth, throat, sinuses, middle ear, or bronchi.

Germaway is a prescription drug. Your doctor will tell you the purpose for which he/she has prescribed you the medicine.

2. What must you know before taking Germaway tablets

Do not use Germaway tablets:

- if you are allergic to penicillin or other ingredients of Germaway tablets (see Section 6 of the package leaflet)
- if you have had a severe, immediate hypersensitivity reaction (such as anaphylaxis) to a medicine belonging to the same group of antibiotics (beta-lactam antibiotics, such as cephalosporin)

Warnings and precautions

Consult your doctor before taking penicillin, if you have experienced dermatitis or other allergic symptoms when using antibiotics or you have atopic dermatitis.

Vomiting and diarrhoea might prevent the drug from being absorbed properly. If symptoms appear, consult your doctor.

Other medicinal products and Germaway

Please tell your doctor or pharmacist about all medicines you are taking. This applies to both prescription medicines and over-the-counter medicines, herbal remedies, and natural products. Also remember to mention if you have recently taken some medicine. The effect of some medicines may change, or they may change the effect of Germaway tablets if they are taken at the same time.

In particular, pay attention to the following kinds of medicinal products:

- the gout suppressant probenecid (may reduce the efficacy of penicillin)
- methotrexate used for the treatment of connective tissue diseases (penicillin may increase its efficacy and adverse reactions)
- guar gum (diabetes drug and anti-cholesterol drug)
- certain antibiotics (for example tetracyclines)
- warfarin, an anticoagulant

In such a case, your doctor might alter your medication or dose, or might require extra blood tests

Also tell your doctor if you have other diseases or allergies.

Germaway with food and drink

Germaway must be taken into an empty stomach so that at least 2 hours have passed from the previous meal and the next meal is at least 30 minutes away.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, or you suspect you are pregnant, consult your doctor or pharmacist before using this medicine.

Driving and using machines

Germaway does not have any detrimental effect on alertness or performance.

3. How Germaway tablets are used

Use this medicine exactly as prescribed by your doctor. If you are unsure, check the instructions from your doctor.

The effect of the drug stays constant when you always take it at the same time of day. This is also the best way to remember to take the drug.

Swallow the tablets with a sufficient amount of fluid, for example, with a glass of water.

Important!

Take the entire course of medicine, even if the symptoms disappear in a few days after you have started the medication. Even is the symptoms are already gone, some of the bacteria might still be able to multiply, and the disease might recur. The remaining bacteria might also develop resistance to antibiotics, which makes them more difficult to kill when the disease recur.

If you take more Germaway tablets than you should

If you have taken a dose that is too high, or your child has accidentally taken the medicine, always contact your doctor, a hospital, or the Poison Information Centre (tel. +358 800 147 111) for a risk assessment and further instructions.

If you forget to take a Germaway tablet

Take the dose you forgot as soon as possible. If the time for the next dose is close, do not take the forgotten dose. Do not take a double dose or two doses immediately after one another.

If you have any questions about the use of this medicine, please consult your doctor or pharmacist.

4. Possible adverse reactions

Like all medicines, Germaway can cause adverse reactions although not everybody gets them.

Stop using the medicine and immediately contact a doctor or the nearest emergency clinic if you experience symptoms suggesting a severe hypersensitivity reaction, such as:

- breathing difficulties or dyspnoea
- skin erythema, itching and swelling, blistering or desquamation
- swelling of the oral mucosa, tongue or throat

If you experience strong or persistent diarrhoea during the treatment or afterward, stop using the medicine and contact a doctor. In such a case, you must not use antidiarrhoeal medication that decreases bowel motility.

Common adverse reactions (up to 1 patient out of 10):

- stomach ache, nausea, or vomiting
- flatulence or diarrhoea

Rare adverse reactions (up to 1 patient out of 1000):

- an allergic reaction that might cause swelling and joint pain, among other symptoms
- severe hypersensitivity reaction (swelling of lips, throat, eyelids, and skin, breathing difficulties, swallowing difficulties)

Reporting adverse reactions

If you notice any adverse reactions, tell your doctor or pharmacist. This also applies to all adverse reactions not listed in this leaflet. You can also report adverse reactions directly (please see the contact information below). By reporting adverse reactions, you can help in increasing our awareness of the safety of this medicinal product.

website: www.fimea.fi
Finnish Medicines Agency Fimea
Adverse drug reaction database
PL 55
FI-00034 FIMEA, Finland

5. How to store Germaway tablets

Keep out of the sight and reach of children.
Do not store above 25 °C. Store in the original package. Sensitive to moisture.

Do not use this medicine after the expiry date stated on the package (Use.last. or EXP). The expiry date means the last day of the month.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Package contents and further information

What Germaway tablets contain

The active substance is phenoxymethylpenicillin, of which one tablet contains 500 000 IU (international units).

The other ingredients are magnesium stearate, macrogol 6000, maltodextrin, povidone, talc, hypromellose, peppermint oil, saccharin sodium, and titanium dioxide (E171).

Description of the medicinal product and package sizes

White or natural white, round tablet with a diameter of around 9 mm.

Package sizes: 20 tablets in a blister package.

Marketing authorisation holder and manufacturer

Medicine Factory Ltd
Tablet Road 1
12345 Medville
Finland

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