

Package leaflet: Information for the user

Aceterin express, 10 mg film-coated tablets Cetirizine hydrochloride

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

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

What is in this leaflet:

1. What Aceterin express is and what it is used for
2. What you need to know before you use Aceterin express
3. How to use Aceterin express
4. Possible side effects
5. How to store Aceterin express
6. Contents of the pack and other information

1. What Aceterin express is and what it is used for

Aceterin express is an anti-allergy medicine and it is used for:

- the symptomatic treatment of seasonal or year-round hay fever (rhinitis) and associated eye inflammation (conjunctivitis);
- the symptomatic treatment of hives (chronic idiopathic urticaria).

2. What you need to know before you use Aceterin express

Do not use Aceterin express:

- if you are allergic to cetirizine hydrochloride or any of the other ingredients of this medicine (listed in section 6), hydroxyzine, or piperazine derivatives;
- if you have severe renal failure (creatinine clearance lower than 10 mL/min);

Warnings and precautions

No significant interaction with alcohol has been observed at treatment dosages. Nevertheless, it is recommended to exercise caution with concomitant use of alcohol.

Caution is required for patients with a predisposition to urinary retention (e.g. spinal injury, enlarged prostate), as cetirizine may increase the risk of urinary retention.

If you suffer from epilepsy or a risk of cramps, talk to your doctor.

Treatment with Aceterin express must be stopped three days before skin tests, as allergy medicines may interfere with a positive reaction in skin tests.

When you stop taking cetirizine, itching and / or hives may occur, even if these symptoms did not occur before starting treatment. The symptoms should recede when restarting the treatment.

Children

Using film-coated tablets in children under the age of 6 is not recommended, as the tablet does not permit adjusting the dosage. It is recommended to use the cetirizine dosage form for children.

Other medicines and Aceterin express

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Cetirizine is not known to interact with other medicines.

Aceterin express with food, drink and alcohol

Food does not have a significant effect on the absorption of cetirizine.

Taking this medicine with alcohol or other agents that affect the central nervous system may result in additional attention loss and reaction disorders.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Caution is advised when prescribing this medicine during pregnancy.

Cetirizine hydrochloride is excreted in breast milk, due to which caution is advised when using Aceterin express while breast-feeding.

Driving and using machines

Clinical studies have shown no reduction in the ability to drive or use machines after using Aceterin express in the prescribed dose. However, if you experience drowsiness, you should refrain from driving, potentially dangerous activities or operating machinery. You should not exceed the recommended dose and you should consider your individual response to the medicine.

Aceterin express contains lactose

If you have been told by your doctor that you have intolerance to some sugars, talk to your doctor before taking this medicine.

Advice for diabetics:

One tablet contains less than 0.01 bread units of carbohydrates.

3. How to use Aceterin express

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose for adults and adolescents over the age of 12 is:

10 mg (one tablet) of Aceterin express per day, preferably in the evening.

Children aged 6–12 years with a weight of 30 kg or more:

10 mg (1 tablet) once a day or 5 mg (half a tablet) 2 times a day (morning and evening).

Children aged 6–12 years with a weight of less than 30 kg:

5 mg (half a tablet) once a day.

Aceterin express 10 mg tablets are not suitable for children under the age of 6 due to the large content of the active substance.

Elderly

The elderly with a normal renal function do not have to reduce dosage.

Renal impairment

For patients with moderate to severe renal impairment, dosage should be adjusted individually, based on renal clearance. Talk to your doctor if you have moderate to severe renal impairment. Aceterin express is contraindicated for patients receiving dialysis (creatinine clearance under 10 mL/min).

Hepatic impairment

If you only suffer from hepatic impairment, adjusting the dose is not necessary. Adjusting the dose is only necessary in the case of concomitant renal impairment (see above).

Method and duration of administration

The tablet should be taken without chewing, with fluid, and preferably in the evening.

Aceterin express can be taken independent of meal times.

The duration of treatment depends on the nature, duration, and dynamics of the complaints, and is decided by your doctor. In the case of hay fever, a treatment duration of 3–6 weeks is usually sufficient; during short periods of pollen release, even just 1 week may be sufficient. In the palliative treatment of asthmatic conditions of allergic origin, experience is only available for a treatment of up to 6 months. Current experience of using tablets containing cetirizine in the case of chronic urticaria and chronic rhinitis is limited to treatment lasting up to 1 year.

Check with your doctor or pharmacist if you are not sure.

If you feel that the effect of Aceterin express is too strong or too weak, talk to your doctor or pharmacist.

If you use more Aceterin express than you should

Talk to your doctor if you feel that you have taken more Aceterin express than you should have. Your doctor will decide which measures to take (if necessary).

The following side effects may occur in the case of overdose: confusion, diarrhoea, dizziness, tiredness, headache, malaise, dilated pupils, rash, restlessness, drowsiness, sleepiness, decreased reaction to external irritants, increased heart rate, trembling and urinary retention.

If you forget to take Aceterin express

Do not take a double dose to make up for a forgotten dose.

If you stop taking Aceterin express

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some very rare side effects may be serious:

Immediately stop using this medicine and immediately talk to your doctor or go to the reception of the nearest hospital if you have any of the following side effects:

- severe allergic reactions, such as sudden difficulties in breathing, speaking and swallowing; swollen lips, neck or face; severe dizziness or fainting, itching, raised skin rash;
- haematoma or bleeding caused by reduction in platelet count.

Other side effects:

The following side effects have been described based on post-marketing experience:

Uncommon side effects (more than 1 patient in 1,000 but fewer than 1 in 100): agitation, paresthesia (prickling sensation or numbness in arms or legs), diarrhoea, itching, skin rash, weakness, fatigue.

Rare side effects (more than 1 patient in 10,000 but fewer than 1 in 1,000): hypersensitivity, aggression, confusion, depression, hallucinations, insomnia, cramps, increased heart rate, changes in hepatic analyses, urticaria, swelling, increased body weight.

Very rare side effects (fewer than 10 patients in 10,000): low platelet count, anaphylactic shock, seizures, impaired taste, abnormal movements (dyskinesia, dystonia), fainting, trembling, abnormal accommodation, hazy vision, nonvoluntary upward movement of the eyeball (oculogyration), angioneurotic swelling, local drug rash, painful and/or difficult urination.

Side effects of **unknown** frequency (cannot be estimated from available data): memory loss or memory problems, increased appetite, suicidal ideation, vertigo, urinary retention, nightmares, inflammation of the liver, acute generalized exanthematous pustulosis (reddening scaly skin rash with subcutaneous nodules and blisters), joint pain.

The following side effects were reported in clinical studies in adults: fatigue, dizziness, headache, abdominal pain, dry mouth, nausea, sleepiness, pharyngitis.

The following side effects were reported in children aged 6 months to 12 years: diarrhoea, sleepiness, rhinorrhoea, fatigue.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via www.ravimiamet.ee. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Aceterin express

Keep this medicine out of the sight and reach of children.

Aceterin express does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Aceterin express contains

- The active substance is cetirizine hydrochloride. One tablet contains 10 mg of cetirizine hydrochloride.
- The other excipients are microcrystalline cellulose, hypromellose, lactose monohydrate, macrogol 4000, magnesium stearate, highly dispersible silica, colouring agent titanium dioxide (E171).

One tablet contains 10 mg of cetirizine hydrochloride.

What Aceterin express looks like and contents of the pack

Aceterin express is a white, biconvex, elongated film-coated tablet with an indented line on one side. The length of the tablet is 10.3 mm, width 4.2 mm, and height 2.8 mm. The tablet may be divided into equal doses.

The original package contains 10 tablets in PVC/aluminium blister packages.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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