

Package leaflet: Information for the user

Prometazin Actavis 25 mg film-coated tablets

promethazine hydrochloride

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet

1. What Prometazin Actavis is and what it is used for
2. What you need to know before you take Prometazin Actavis
3. How to take Prometazin Actavis
4. Possible side effects
5. How to store Prometazin Actavis
6. Content of the pack and other information

1. What Prometazin Actavis is and what it is used for

Prometazin Actavis contains a medicine called promethazine hydrochloride. It belongs to a group of medicines called phenothiazines. It works by blocking the natural substance histamine in your body that causes itching during an allergic reaction. This medicine also has a sedative effect.

Prometazin Actavis can be used in the following situations:

- short-term treatment of sleep disorders
- short-term treatment of anxiety symptoms
- to help you feel more relaxed before an operation or a dental procedure
- to treat or stop motion sickness (e.g. sea sickness)
- to treat itchiness of the skin and allergies
- to treat or stop you feeling sick and dizzy

2. What you need to know before you take Prometazin Actavis

Do not take Prometazin Actavis

- if you are allergic to promethazine hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- if you are taking a medicine for depression belonging to a group of medicines called monoamine oxidase inhibitors (MAOIs). Also, do not take Prometazin Actavis if you have stopped taking one of these MAOI medicines within the last 14 days. If you are not sure, ask your doctor or pharmacist (see “Other medicines and Prometazin Actavis” section below).

Prometazin Actavis should not be given to children under 6 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before taking Prometazin Actavis. This is particularly important if you:

- have any serious heart problems
- have any personal or family history of heart disease
- have an irregular heartbeat
- suffer from severe dizziness, drowsiness or headache
- suffer from an enlarged prostate
- have a stomach blockage or have difficulty passing water
- suffer from severe muscle weakness (myasthenia gravis)
- have liver problems
- are at risk of stroke
- have problems with your heart rhythm
- if you have/have had problems with alcohol, drug or medicine abuse

Tell your doctor immediately if you experience a combination of fever, sweating, stiff muscles, feeling very drowsy or faint (a condition called “neuroleptic malignant syndrome”). Immediate medical treatment may be needed.

Due to dryness of the mouth (which is a normal side effect), there is a risk of dental and oral mucosal damage, especially after long-term use. Consequently, you should brush your teeth carefully twice daily with a fluoride toothpaste while taking this medicine.

Treatment with Prometazin Actavis can lead to problems for contact lens wearers as a result of dry eyes.

Taking Prometazin Actavis may affect the results of urine tests for pregnancy which may lead to a false-positive or false-negative result.

If you are not sure whether any of the above apply to you, talk to your doctor or pharmacist before taking Prometazin Actavis.

Other medicines and Prometazin Actavis

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

Do not take this medicine, and tell your doctor or pharmacist, if you are taking or have taken the following in the last 2 weeks:

Some medicines for depression called monoamine oxidase inhibitors (MAOIs). If you are not sure, ask your doctor or pharmacist

It is also particularly important to tell your doctor or pharmacist if you are taking medicines used for:

- irritable bowel syndrome, asthma or weak bladder (anticholinergic medicines) as these can increase the risk of dizziness, dry mouth and blurred vision
- heart rhythm disturbances and other heart conditions (e.g. flecainide, amiodarone, quinidine and beta-blockers)
- treatment of bacterial infections (e.g. certain antibiotics such as moxifloxacin and erythromycin)
- treatment of fungal infections (e.g. terbinafine)
- pain or drug dependence (e.g. methadone, morphine or morphine-like medicines)
- prevention of malaria (mefloquine)
- intestinal disease (e.g. cisapride)

- mental disorders (e.g. lithium and neuroleptics such as haloperidol, clozapine and risperidone)
- depression (e.g. tricyclic antidepressants, selective serotonin reuptake inhibitors (SSRIs) such as paroxetine and fluoxetine)
- anxiety (e.g. diazepam)
- sleeping problems (e.g. zolpidem)
- epilepsy

Also tell your doctor or pharmacist if you are taking, have recently taken or might take any of the following:

- medicines that can affect your heart rhythm

Avoid concomitant treatment with some diuretics (thiazide diuretics), since these can reduce the potassium content in blood and thus increase the risk of heart rhythm disturbances.

Avoid concomitant treatment with anti-anxiety medicines, medicines for sleep problems, strong painkillers (opioids) and other sedative medicines. This can lead to extreme fatigue and unconsciousness, which can be life threatening.

Prometazin Actavis with food, drink and alcohol

Do not drink alcohol while you are taking Prometazin Actavis. This can lead to extreme fatigue and unconsciousness, which can be life threatening.

Pregnancy and breast-feeding

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 taking this medicine.

Pregnancy:

Your doctor will advise whether you should use Prometazin Actavis during pregnancy.

Stop taking Prometazin Actavis 2 weeks before expected delivery as there may otherwise be a risk of respiratory effects on the newborn.

Breast-feeding

It is unknown whether promethazine hydrochloride passes into breast milk and a risk of effect on the child cannot be excluded. Therefore consult a doctor before use during breast-feeding.

Driving and using machines

Reactions may be impaired during treatment with Prometazin Actavis and difficulties adjusting between near and far vision may occur. This should be taken into consideration when alertness is required, for example when driving. These effects may still occur the following morning. Make sure you are not affected before you drive or operate machinery.

Prometazin Actavis contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Prometazin Actavis

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

The dose will be determined by your doctor who will customise it for you. Do not exceed the dose

indicated by your doctor. The doctor should prescribe the lowest effective dose for the shortest time possible.

The usual dose is:

Short-term treatment of sleep disorders:

Adults: 25-50 mg 1-2 hours before bedtime.

Children 6-17 years-of-age: 20-25 mg 1-2 hours before bedtime.

Sometimes the medication is discontinued every third or fourth night.

Short-term treatment of anxiety symptoms:

Adults: 25-50 mg, 1-3 times a day.

Before an operation or a dental procedure:

Adults: 25-50 mg one hour before treatment; if necessary, the same dose may be taken the evening before treatment.

Children 6-12 years-of-age and adolescents 13-17 years: 25 mg one hour before treatment; if necessary, the same dose may be taken the evening before treatment.

Motion sickness:

Adults: 25 mg, 1-2 hours before the trip or alternatively the evening before the trip. If needed, two extra doses can be taken in a 24-hour period.

Adolescents 13-17 years: 20-25 mg, 1-2 hours before the trip or alternatively the evening before the trip. If needed, two extra doses can be taken in a 24-hour period (maximum daily dose 60 mg).

Allergic conditions:

Adults: 25-50 mg at night.

For dosages, which cannot be achieved with Prometazin Actavis other strengths of promethazine medicinal products are available.

If you take more Prometazin Actavis than you should

If you or your child takes more Prometazin Actavis than you should, contact your doctor at once or go to the nearest hospital casualty department. Take the medicine pack with you. This is so the doctor knows what you have taken.

Symptoms of overdose may include fatigue, loss of consciousness, tremors, twitching, headache, hallucinations, seizures, palpitations, redness of skin, high body temperature, large pupils, difficulty urinating, nausea, vomiting. Overdosage can be life threatening, especially if alcohol, drugs and/or certain medicines are taken at the same time (see "Other medicines and Prometazin Actavis")

If you forget to take Prometazin Actavis

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

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

4. Possible side effects

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

Stop taking Prometazin Actavis and see a doctor or go to a hospital straight away if you notice any of the following side effects:

Rare (may affect up to 1 in 1000 people)

- Liver problems that may cause the eyes or skin to go yellow (jaundice)
- Very fast or uneven heartbeat or chest pains

Not known (frequency cannot be estimated from the available data)

- Abnormal electrical activity of the heart that affects its rhythm, including life-threatening rhythm disturbance
- A serious reaction with fever, rigid muscles, changing blood pressure and coma (neuroleptic malignant syndrome)

Other possible side effects:

Common (may affect up to 1 in 10 people)

- Dry mouth.
- Drowsiness. Since Prometazin Actavis is usually taken at night, you may feel a little drowsy the following morning. This effect should disappear after a few days treatment.

Uncommon (may affect up to 1 in 100 people)

- Dry eyes
- Difficulty adjusting between near and far vision
- Constipation
- Difficulty urinating

Not known (frequency cannot be estimated from the available data)

- Light tremor, stiffness, shaking in e.g. hands and fingers, twitches in the face, grimacing and strange movements of the tongue. Sometimes, a special form of nervousness may occur, e.g. difficulty sitting still.
- Low levels of blood platelets (which can lead to bleeding and bruising)
- Restlessness
- Hallucinations
- Aggression

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 [the national reporting system listed in Appendix V*](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Prometazin Actavis

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

Do not use this medicine after the expiry date which is stated on the blister and carton after EXP.

This medicinal product does not require any special storage conditions.

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 Prometazin Actavis contains

- The active substance is promethazine hydrochloride
- The other ingredients are:
Tablet core: microcrystalline cellulose, calcium hydrogen phosphate dihydrate, sodium starch glycolate, stearic acid, magnesium stearate.
Tablet coating: hypromellose (E464), macrogol (E1521), titanium dioxide (E171), talc.

What Prometazin Actavis looks like and contents of the pack

Prometazin Actavis 25 mg film-coated tablets are white, oval shaped, 9.8 mm x 6.2 mm biconvex, marked with “C25” on one side and plain on the other side, available in blister packs.

Pack sizes

2, 4, 8, 12, 16, 30, 50, 100 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicine is authorised in the Member States of the European Economic Area under the following names:

Denmark	Prometazin Actavis
Sweden	Prometazin Actavis
Iceland	Prometazin Actavis

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[To be completed nationally]