

## **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. Like many histamine-blocking agents, it has a sedative effect.

Prometazin Actavis can be used in the following situations:

- to treat sleep disorders
- to treat severe anxiety
- 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
- to help treat alcohol and drug abuse

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

#### **Do not take Prometazin Actavis:**

- if you are allergic to promethazine hydrochloride or to any of the other ingredients in 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 5 years of age.

### **Warnings and precautions**

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

- 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
- have a risk of stroke
- have problems with your heart rhythm

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, have recently taken or might take 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)
- 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)

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.

### **Prometazin Actavis with food, drink and alcohol**

Do not drink alcohol while you are taking Prometazin Actavis.

### **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.

### **Driving and using machines**

Reactions may be impaired during treatment with Prometazin Actavis. 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.

### **/.../ 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.

### **The usual dose is:**

#### *Sleep disorders:*

Adults: 25-50 mg at night.

Children 5-12 years-of-age: 25 mg at night.

Sometimes the medication is discontinued every third or fourth night.

#### *Severe anxiety and hyperactivity:*

Adults: 25-50 mg, up to 400-500 mg per 24-hour period.

#### *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: 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.

#### *Allergic conditions:*

Adults: 25-50 mg at night.

### **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.

### **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:**

- Liver problems that may cause the eyes or skin to go yellow (jaundice)
- Jerky movements and problems such as slowness, muscle stiffness, trembling and feeling restless
- Very fast or uneven heartbeat or chest pains

**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

### **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.

This medicinal product does not require any special storage conditions.

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

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*

Blisters:

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 medicinal product is authorised in the Member States of the EEA under the following names:**

Sweden	Prometazin Actavis
Denmark	Prometazin Actavis
Iceland	Prometazin Actavis

**This leaflet was last revised in**  
05/2020