

Package leaflet: Information for the patient

Valoid® 50 mg Tablets (cyclizine 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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Valoid 50 mg Tablets. It will be referred to as Valoid Tablets for ease hereafter.

What is in this leaflet

1. What Valoid Tablets are and what they are used for
2. What you need to know before you take Valoid Tablets
3. How to take Valoid Tablets
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1. What Valoid Tablets are and what they are used for

Each tablet contains 50 mg of the active ingredient, cyclizine hydrochloride.

Valoid Tablets belongs to a group of medicines called antihistamines. These are used in adults and children aged over 6 years to block the effects of substances called histamine and acetylcholine in your body, which can make you feel sick (nausea) or actually vomit. Valoid Tablets are used for travel or motion sickness, and nausea which can be caused by radiotherapy or some medicines.

Some ear disorders, for example Meniere's disease, can cause loss of balance. Valoid Tablets are used to treat the dizziness and vomiting which can come with this.

2. What you need to know before you take Valoid Tablets

Do not take Valoid Tablets if you:

- are allergic to cyclizine hydrochloride or any of the other ingredients of this medicine (listed in section 6). Allergic reactions include mild symptoms such as itching and / or rash. More severe symptoms include swelling of the face, lips, tongue and / or throat with difficulty in swallowing or breathing

- have been drinking alcohol. The anti-vomiting properties of cyclizine may increase the toxicity of alcohol.

If any of these apply to you, or if you are not sure, do not take Valoid Tablets. Speak to your doctor or pharmacist before taking this medicine.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Valoid Tablets if you:

- suffer from glaucoma (eye disease caused by too much pressure within the eye)
- suffer from urinary retention (experience difficulty passing urine)
- suffer from stomach cramps, abdominal pains or constipation
- have any liver problems
- have a phaeochromocytoma (tumour of the medulla of the adrenal glands)
- have high blood pressure
- have epilepsy
- are a man, and suffer from an enlarged prostate gland
- are being treated for a weak heart or heart beat (heart failure)
- suffer from an inherited disorder which can lead to sensitivity to sunlight (porphyria)
- have any problems with your muscles or the nerves that control them.

Children

Valoid Tablets are not recommended for children less than 6 years of age.

Other medicines and Valoid Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, especially the following:

- medicines for problems such as depression, anxiety or difficulty sleeping
- strong painkillers such as pethidine
- any medicine which belongs to a group of medicines called anticholinergics
- certain antibiotics called aminoglycosides such as gentamicin and neomycin.

Valoid Tablets with food, drink and alcohol

Alcohol should be avoided when taking Valoid Tablets.

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 taking this medicine. The active ingredient of Valoid Tablets is excreted in breast milk.

Driving and using machines

Valoid Tablets may cause drowsiness in some people. You should avoid driving until you have found out how Valoid Tablets affect you. If they make you feel sleepy, do not drive or operate machinery.

Valoid Tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Valoid Tablets

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

Adults and children over 12 years of age

The recommended dose is one tablet up to three times a day.

Use in children 6 to 12 years of age

The recommended dose is half a tablet up to three times a day. The tablet can be divided into equal doses along the line scored on one side of the tablet.

Children under 6 years

Valoid Tablets are not recommended for children less than 6 years of age.

Take the tablets with a little water to make swallowing easier.

If you take more Valoid Tablets than you should

If you take more tablets than your doctor has told you to, seek medical advice urgently. An overdose could cause a dry mouth nose and throat, blurred vision, a faster heart beat, difficulties when passing urine, feeling sleepy, dizziness, difficulties controlling movements, weakness, feelings of excitement, disorientation, impaired judgement, hallucinations, fits, a high fever and breathing difficulties.

If you forget to take Valoid Tablets

If you forget to take a dose, take another one as soon as you remember and then go on as before.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Please tell your doctor or pharmacist if you have any of the following while you are taking Valoid Tablets.

If you notice:

- itching or skin rashes
- swelling of the face, lips or throat
- difficulty in breathing or wheeziness

stop taking the tablets and tell your doctor immediately. These may be signs of an allergic reaction.

The following side effects are reported for either compound with a not known frequency (frequency cannot be estimated from the available data):

- drowsiness
- lack of coordination
- headache
- a dry mouth, nose or throat
- blurred vision
- involuntary rolling of the eyes
- fast or irregular heartbeat
- difficulty in passing water
- constipation
- heartburn (reflux)
- nausea
- vomiting
- diarrhoea
- stomach pain
- loss of appetite
- restlessness
- nervousness
- euphoria
- difficulty in sleeping
- ringing in the ears
- seeing or hearing things that are not really there (hallucinations)
- decrease in muscle tone
- unusual movements, particularly of your hands, arms or legs
- muscle twitches, spasms or tremors
- seizures
- being confused, disorientated or unaware
- dizziness
- feeling weak
- decreased consciousness
- temporary difficulty in speaking
- high blood pressure
- low blood pressure
- pins and needles
- yellowing of the skin and the whites of your eyes (jaundice)
- a red or brownish patch which appears at the same spot each time you take the medicine
- an increased sensitivity to sunlight (photosensitivity)
- inflammation of the liver (hepatitis) or problems with the liver
- reduced rate of breathing (apnoea)
- a reduction in the production of a type of white blood cell making infection more likely (agranulocytosis).

If you feel very tired, experience unexpected bruising or bleeding or more infections (such as colds or sore throats) than usual please tell your doctor. Your doctor may decide to conduct blood tests periodically as a result of these symptoms.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Valoid Tablets

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

Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP . 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 Valoid Tablets contain

The active substance is cyclizine hydrochloride. Each tablet contains 50 mg of cyclizine hydrochloride.

The other ingredients are lactose monohydrate, potato starch, acacia and magnesium stearate.

What Valoid Tablets look like and contents of the pack

Valoid Tablets are white with a single line scored on one side and the marking “T4A” on the same side.

Valoid Tablets are available in glass or polyethylene bottles containing 100 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Amdipharm Ltd.
Unit 17
Northwood House
Northwood Crescent
Northwood
Dublin 9
D09 V504
Ireland

Manufacturer:

Cenexi SAS
52 rue Marcel et Jacques Gaucher
94120 Fontenay sous Bois

France

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