Package leaflet: Information for the patient

Pyridoxine hydrochloride 50mg tablets

(Pyridoxine 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).

The full name of your medicine is pyridoxine hydrochloride 50mg tablets. It is referred to as pyridoxine tablets in the rest of this leaflet.

In this leaflet:

- 1. What pyridoxine tablets are and what they are used for
- 2. What you need to know before you take pyridoxine tablets
- 3. How to take pyridoxine tablets
- 4. Possible side effects
- 5. How to store pyridoxine tablets
- 6. Contents of the pack and other information

1. What pyridoxine tablets are and what they are used for

The active substance in pyridoxine tablets is pyridoxine hydrochloride, which is Vitamin B6.

It is used to treat low levels of Vitamin B6 in the body and in the treatment of a condition called idiopathic sideroblastic anaemia where the red cells in the blood do not form properly.

Pyridoxine tablets can also be used to treat damage to the nerves (peripheral neuritis) caused by isoniazid, a drug used to treat tuberculosis.

2. What you need to know before you take pyridoxine tablets

Do not take pyridoxine tablets if:

• you are allergic to pyridoxine hydrochloride or any of the other ingredients of this medicine (listed in section 6).

If the above statement applies to you, you should not take pyridoxine tablets.

Talk to your doctor before taking pyridoxine tablets if:

• the patient is a child. Pyridoxine tablets are not reccomended for children.

Other medicines and pyridoxine tablets:

- Taking another medicine while you are taking pyridoxine tablets can affect how it or the other medicine works. Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including those you may have bought yourself without a prescription.
- Please check with your doctor if you are taking any of the following (or any other medication):
- levodopa, a drug used in the treatment of Parkinson's disease
- isoniazid, a drug used to treat tuberculosis
- oral contraceptives
- penicillamine, a drug used to treat arthritis and other conditions.

If you have any doubts about whether you should take this medicine then discuss matters with your doctor before taking it.

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 operating machines

Pyridoxine tablets do not affect the ability to drive or operate machinery.

3. How to take pyridoxine tablets

Your doctor will decide the dose which is best for you. Always follow your doctor's instructions completely and also follow any special instructions or warnings which the pharmacist has put on the dispensing label. Contact your doctor if your symptoms worsen or do not improve. If you do not understand, or are in any doubt, ask your doctor or pharmacist.

Unless instructed differently, take your tablets with a glass of water.

The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

For the treatment of low levels of Vitamin B6 in the body The usual dose in adults is 50 to 150mg daily in divided doses.

For the treatment of idiopathic sideroblastic anaemia The usual dose in adults is 100 to 400mg daily in divided doses.

For the treatment of nerve damage (peripheral neuritis) caused by isoniazid The usual adult dose is 50mg three times a day. In adults, this dosage form is not suitable for prophylaxis.

Elderly

If you are elderly you will require similar doses to those given above.

Children

Pyridoxine tablets are not recommended for use in children.

If you take more pyridoxine tablets than you should

If you accidentally take too many tablets, contact your doctor, pharmacist or nearest hospital casualty department. Take this leaflet and any remaining tablets with you to show the doctor or pharmacist.

If you miss a dose of pyridoxine tablets

If you forget to take a dose, take another as soon as you remember. If it is almost time for your next dose, then do not take the missed dose at all. Do not take a double dose to make up for a forgotten tablet.

Stopping pyridoxine tablets

You should continue to take pyridoxine tablets for as long as your doctor tells you to. Do not stop taking the medicine without talking to your doctor first.

4. Possible side effects

Like all medicines pyridoxine tablets can cause side effects, although not everybody gets them.

If you take large doses of pyridoxine tablets for a long time, you may develop problems with your nerves (peripheral neuritis). One of the symptoms of peripheral neuritis can be pins and needles.

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 Yellow Card Scheme at http://www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5.How to store pyridoxine tablets

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

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

Store below 25°C.

Store in the original blister in order to protect from light and moisture. Do not transfer the tablets to another container.

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

6.Contents of the pack and other information

What pyridoxine tablets contain

- The active substance in pyridoxine tablets is pyridoxine hydrochloride. Each tablet contains 50mg of the active substance.
- The other ingredients are calcium phosphate dibasic anhydrous, starch maize, sodium lauryl sulphate and magnesium stearate.

<u>What pyridoxine tablets look like and contents of the pack</u> White to off-white round shaped tablets with a score line on one side and plain on the other.

The tablets are packed in OPA/ALU/PVC blister of 10 or 14 tablets. Pack sizes: 10, 14, 20, 28, 30, 40, 50, 56, 60, 70, 80, 84, 90 and 112 tablets. Not all pack sizes may be marketed.

Marketing Authoisation Holder Somex Pharma, Ilford, Essex, IG3 8BS, UK.

Manufacturer Kleva Pharmaceuticals SA, 189 Parnithos Avenue, 136 75 Acharnai, Athens, Greece.

This leaflet was last revised in September 2021.

Other sources of information:

To request a copy of this leaflet in braille or large print please call, 020 8590 9399 (UK Only).

