

WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.**

The medicine may be authorised for additional or different uses by national medicines regulatory authorities.

* https://extranet.who.int/pqweb/sites/default/files/documents/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[TB383 trade name][†]
Pyridoxine hydrochloride

*The warnings and instructions in this leaflet are intended for the person taking the medicine.
If you are a parent or carer responsible for giving the medicine to someone else such as a child,
you will need to apply the instructions accordingly.*

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 questions about the medicine, ask your health care provider.
- 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 seem to be the same as yours.
- If you are concerned about any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [TB383 trade name] is and what it is used for
2. What you need to know before you take [TB383 trade name]
3. How to take [TB383 trade name]
4. Possible side effects
5. How to store [TB383 trade name]
6. Contents of the pack and other information

1. What [TB383 trade name] is and what it is used for

[TB383 trade name] contains the active substance pyridoxine.

Pyridoxine is also known as vitamin B₆. It is used for treating peripheral neuropathy (damage to the nerves) caused by isoniazid, a tuberculosis (TB) medicine. Peripheral neuropathy can cause abnormal sensation on the skin, pain, and loss of balance and co-ordination.

In children, pyridoxine is used to prevent side effects of high doses of isoniazid. It can also be given to children treated with isoniazid for certain types of tuberculosis, such as tuberculosis in the brain (tuberculous meningitis) or in the bones or joints (osteoarticular tuberculosis).

2. What you need to know before you take [TB383 trade name]

Do not take [TB383 trade name] if:

- you are allergic to pyridoxine or any of the other ingredients of [TB383 trade name] (see list under 'What [TB383 trade name] contain' in section 6)

If the above applies to you, you should not take [TB383 trade name].

Taking other medicines

Taking another medicine while you are taking [TB383 trade name] can affect how it or the other medicine works. Tell your health care provider if you are taking any of the following:

- combined hormonal contraceptives, birth control medicines
- cycloserine, a medicine for treating tuberculosis

[†] Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

- hydralazine, a medicine used for treating high blood pressure and some heart conditions
- levodopa, a medicine used for treating Parkinson's disease
- penicillamine, used to treat rheumatoid arthritis
- phenobarbital, phenytoin and primidone, medicines used for treating epilepsy.

Also tell your health care provider if you are taking any other medicine or if you have recently taken other medicines. Talk to your health care provider before you take any other medicine during your treatment with [TB383 trade name].

If you have any doubts about taking this medicine talk to your health care provider before taking it.

Pregnancy and breast-feeding

You can take [TB383 trade name] during pregnancy or if you are breast-feeding. However, tell your health care provider if you are pregnant or wish to become pregnant, or you wish to breast-feed, whilst taking [TB383 trade name].

Driving and operating machines

Pyridoxine Tablets do not have an effect on your ability to drive or operate machinery.

3. How to take [TB383 trade name]

Your health care provider will decide the right dose of [TB383 trade name] for you. Speak with your health care provider if you have symptoms of peripheral neuropathy or they do not get better. Symptoms of peripheral neuropathy include abnormal sensations (such as numbness, tingling, burning and 'pins and needles'), pain even with light touch and loss of balance and co-ordination of movement).

The usual recommended doses are shown below. Take your tablets with a drink of water. You can take the tablets with food or between meals. It is best to take them at around the same time every day.

If you need more information, ask your health care provider.

Treating peripheral neuropathy caused by isoniazid

	Usual recommended dose
Adults	1 tablet once or twice daily but may be increased up to 4 tablets a day in divided doses
Young people aged 12 to 18 years	½ to 1 tablet 2 or 3 times a day
Children aged up to 12 years	1 tablet once or twice daily

Preventing peripheral neuropathy that may be caused by isoniazid

For patients taking isoniazid who are vulnerable to peripheral neuropathy, another pyridoxine medicine (such as tablets containing pyridoxine 10 mg) is more suitable.

Preventing side effects of isoniazid in children

	Usual recommended dose
Children aged over 4 years	½ tablet once a day*
Children aged under 4 years	¼ tablet once a day†
* Use only tablets that can be broken into two equal halves	
† Use only tablets that can be broken into equal quarters	

If you take more [TB383 trade name] than you should

If you take too many tablets by mistake, contact your health care provider. Take this leaflet and any remaining tablets with you to show to the health care provider.

If you miss a dose of [TB383 trade name]

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

If you have vomited within 1 hour of taking [TB383 trade name], then take an extra dose. If you have vomited more than an hour after taking the dose, then do not take an additional dose until the next dose is due

Stopping [TB383 trade name]

Continue taking [TB383 trade name] for as long as your health care provider tells you to. Do not stop taking the medicine without checking with your health care provider.

Where patients are unable to swallow tablets, such as children, then an extemporaneous preparation is done as follows:

1. Take the required dose of [TB383 trade name], as advised by your health care provider and place it in a small bowl.
2. Place a small amount of water such as a teaspoonful (5ml) into the bowl and stir until the tablet disintegrates
3. Add a small amount of soft food such as yogurt into the bowl and mix to mask the taste
4. Feed the infant/child all of the mixture

Repeat these steps every time you need to give the medicine.

If you have any further questions on the use of this medicine, ask your health care provider.

4. Possible side effects

If you take large doses of [TB383 trade name] for a long time you may get 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 health care provider. This includes unwanted effects not listed in this leaflet. If available, you can also report side effects directly through the national reporting system. By reporting side effects you can help improve understanding about the safety of this medicine.

5. How to store [TB383 trade name]

For Strip pack:

Store in a dry place below 30°C, protected from light.

For HDPE Container pack:

Store in a dry place below 30°C, protected from light. Should be used within 90 days, once opened.

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

Do not use this medicine after the expiry date "EXP" stated on the label, carton or bottle. The expiry date refers to the last day of that month.

Do not use this medicine if you notice that it is different from the description below.

Do not throw away any medicines in wastewater or in household waste. Ask your health care provider 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 [TB383 trade name] contains

- The active ingredient is pyridoxine hydrochloride
- The other ingredients of [TB383 trade name] are microcrystalline cellulose, colloidal anhydrous silica, sodium starch glycolate, anhydrous citric acid and magnesium stearate

What [TB383 trade name] looks like and contents of the pack

[TB383 trade name] is a white, circular, flat face, bevelled edged, uncoated tablet having a scoreline on one side and plain surface on the other side.

[TB383 trade name] are packaged in:

Strip pack of 9 x 10's, 10 x 10's

Strip of 10 tablets of Plain 40 micron Aluminium foil (150 gauge polyethylene film width 180 mm (top foil) and (bottom foil) and such 9 or 10 strips are packed in carton along with pack insert.

Container pack: 1000 Tablets

1000 Tablets packed in HDPE container, round white, HDPE 250cc, 53 mm neck continues thread closure with pulp and HS 121 white liner. Should be used within 90 days, once opened.

Supplier and Manufacturer

Supplier

Macleods Pharmaceuticals Ltd.
304, Atlanta Arcade,
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Fax: 0091 22 2821 6599
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Manufacturer

Macleods Pharmaceuticals Limited
Unit II, Phase-II & III, Plot No. 25-27
Survey No 366
Premier Industrial Estate
Kachigam
Daman, 396 210
India

For any information about this medicine, contact the supplier:

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Detailed information on this medicine is available on the World Health Organization (WHO) website:
<https://extranet.who.int/pqweb/medicines>