

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/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[TB383 trade name][†]

Pyridoxine hydrochloride

If you are a carer or parent looking after the person who takes this medicine, use this leaflet to give the medicine correctly and take note of the warnings and side effects.

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 is for you only. Do not pass it on to others. It may harm them, even if their illness seems 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, which is also known as vitamin B₆. It is used for treating damage to the nerves (peripheral neuropathy) caused by the tuberculosis (TB) medicines isoniazid, cycloserine and terizidone. This nerve damage can cause odd feelings in your skin like tingling or pins and needles, pain, or loss of balance and co-ordination.

Pyridoxine may also be used for preventing nerve damage in patients taking high doses of these medicines, or in patients who are considered at special risk of nerve damage.

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)

Taking other medicines

Taking other medicines while you are taking [TB383 trade name] may affect the action of [TB383 trade name], or [TB383 trade name] may affect their action. Tell your health care provider if you are taking any of the following:

- oral contraceptive pills
- 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

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

- phenobarbital, phenytoin and primidone, medicines used for treating epilepsy.

Your health care provider will normally recommend this medicine along with your TB medicines. Tell your health care provider if your TB medication changes, or if you are taking or have recently taken any other medicines. Also tell your health care provider if you plan to 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. Tell your health care provider if you are pregnant or wish to become pregnant, or you wish to breast-feed, while taking [TB383 trade name].

Driving and using machines

[TB383 trade name] is not likely to affect your ability to drive or operate machinery.

However, make sure you feel well enough to take on any skilled tasks.

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 your symptoms of peripheral neuropathy 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.

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 to take half tablet of [TB383 trade name], break the tablet in two equal halves along the break-line in the middle of the tablet.

For patients unable to swallow tablets, such as small children:

- take the required dose of [TB383 trade name] and place it in a small bowl
- place a small amount of water such as a teaspoonful (5 ml) into the bowl and stir until the tablet breaks up completely
- add a small amount of soft food such as yogurt into the bowl and mix together – this is to hide the taste of the medicine
- feed the child all of the mixture right away

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

Usual dose

Treating nerve damage caused by TB medicines

Adults and adolescents

In adults and adolescents, the usual dose of this medicine is between 1 and 4 tablets daily. Your health care provider will tell you how many tablets to take.

Children aged up to 10 years

When treating nerve damage caused by TB medicine, the usual recommended doses are based on the child's weight as follows:

Child's weight	Number of tablets
3 to less than 6 kg	Use another pyridoxine medicine*
6 to less than 10 kg	½ a tablet a day

10 to less than 15 kg	1 tablet a day
15 to less than 20 kg	1½ tablets a day
20 to less than 25 kg	2 tablets a day
25 to less than 30 kg	2½ tablets a day

* Pyridoxine medicines (such as tablets containing 10 mg) are more suitable.

Preventing nerve damage that may be caused by TB medicines

To reduce the risk of nerve damage that may be caused by TB medicine, the dose of [TB383 trade name] depends on your age and weight; in children it also depends whether they are malnourished or living with HIV. The usual doses are as follows:

Adults and adolescents

The usual dose is ½ a tablet a day.

Children aged up to 10 years

Child's weight	Number of tablets
3 to less than 10 kg	Use another pyridoxine medicine*
10 to less than 20 kg	½ a tablet a day
20 to less than 30 kg	1 tablet a day

* Pyridoxine medicines (such as tablets containing 10 mg) are more suitable.

Malnourished children and children living with HIV: In these patients, lower doses of this medicine should be used, as shown below:

Child's weight	Number of tablets
3 to less than 20 kg	Use another pyridoxine medicine*
20 to less than 30 kg	½ a tablet a day

* Pyridoxine medicines (such as tablets containing 10 mg) are more suitable.

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 so that you can easily describe what you have taken.

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.

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 a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

5. How to store [TB383 trade name]

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

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

This medicine should be used within 90 days, once the bottle is opened.

Do not use this medicine after the expiry date stated on the bottle, carton, blister or strip pack, after “EXP”. The expiry date refers to the last day of that month.

Do not use this medicine if you notice visible signs of deterioration or that it is different from the description below.

Do not throw away any medicines in wastewater or 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 50 mg.
 - The other ingredients of [TB383 trade name] are microcrystalline cellulose, colloidal anhydrous silica, sodium starch glycolate, anhydrous citric acid and magnesium stearate.
- There is too little sodium in this medicine to have any effect, even if you are on a low-sodium diet.

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

[TB383 trade name] is a white to off-white, circular, flat-faced, bevelled edge, uncoated tablet, having a break line on one side and plain surface on the other side.

The tablet can be divided into equal doses.

[TB383 trade name] is available as:

- Aluminium strip pack of 10 tablets. Ten (10) or nine (9) such strips are packed in a carton, along with a package insert, i.e., 10 x 10 tablets or 9 x 10 tablets.
- Round, white plastic (HDPE) bottle, closed with a white plastic (HDPE) closure. Each bottle contains 1,000 tablets.

Supplier

Macleods Pharmaceuticals Limited

304, Atlanta Arcade Marol

Church Road

Andheri (East) 400 059

Mumbai, India

Tel : + 91 022 66 76 28 00

Fax: + 91 022 2821 65 99

E-mail: exports@macleodspharma.com, vijay@macleodspharma.com, sjadhav@macleodspharma.com

Manufacturer

Macleods Pharmaceuticals Limited
Unit 2, Phase II & Phase III, Plot No. 25-27,
Survey No 366
Premier Industrial Estate
Kachigam, Daman, 396 210
India
Tel: + 91 0260 2244337
Fax: + 91 0260 2241565
Email: nishata@macleodspharma.com

For any information about this medicine, contact the local representative of the supplier.

This leaflet was last revised in October 2025.

Detailed information on this medicine is available on the World Health Organization (WHO) website:
<https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products>