

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

[TB413 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 [TB413 trade name] is and what it is used for
2. What you need to know before you take [TB413 trade name]
3. How to take [TB413 trade name]
4. Possible side effects
5. How to store [TB413 trade name]
6. Contents of the pack and other information

1. What [TB413 trade name] is and what it is used for

[TB413 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 [TB413 trade name]

Do not take [TB413 trade name] if:

- you are allergic to pyridoxine or any of the other ingredients of [TB413 trade name] (see list under 'What [TB413 trade name] contain' in section 6)

Taking other medicines

Taking other medicines while you are taking [TB413 trade name] may affect the action of [TB413 trade name], or [TB413 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 [TB413 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 [TB413 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 [TB413 trade name].

Driving and using machines

[TB413 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 [TB413 trade name]

Your health care provider will decide the right dose of [TB413 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 a tablet of [TB413 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 [TB413 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

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	1½ tablets a day
6 to less than 10 kg	3 tablets a day
10 to less than 15 kg	5 tablets a day*
15 kg or more	Use another pyridoxine medicine

*A medicine containing 50 mg pyridoxine may be recommended instead by your health care provider to reduce the number of tablets you have to take.

Adults and adolescents

Your health care provider will normally prescribe a different medicine containing more pyridoxine, to ensure you get the right dose and reduce the number of tablets you need to take.

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 [TB413 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 1 to 2½ tablets a day.

Children aged up to 10 years

Child's weight	Number of tablets
3 to less than 6 kg	½ a tablet a day
6 to less than 10 kg	1 tablet a day
10 to less than 15 kg	2 tablets a day
15 to less than 20 kg	3 tablets a day
20 to less than 25 kg	4 tablets a day
25 to less than 30 kg	5 tablets a day*

*A medicine containing 50 mg pyridoxine may be recommended instead by your health care provider to reduce the number of tablets you have to take.

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 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

If you take more [TB413 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 [TB413 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 [TB413 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 [TB413 trade name]

Continue taking [TB413 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 [TB413 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 [TB413 trade name]

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

Do not use this medicine after the expiry date: EXP as stated on the carton .The expiry date refers to the last day of that month.

Do not use this medicine if you notice 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 [TB413 trade name] contains

- The active ingredient is pyridoxine hydrochloride
- The other ingredients of [TB413 trade name] are microcrystalline cellulose, colloidal anhydrous silica, sodium starch glycolate 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 [TB413 trade name] looks like and contents of the pack

[TB413 trade name] is a white to off white, round, uncoated tablets. They are biconvex (rounded on top and bottom) with a flat edge. The tablets have a break line on one side and are plain on the other side.

[TB413 trade name] is packaged in aluminium foil strip packs, each containing 10 tablets. Available in cartons of 10x10, 50x10 or 100x10 tablets.

Supplier and Manufacturer

Supplier

S Kant Healthcare Ltd.
3-A, Shiv Sagar Estate, North Wing,
Dr. Annie Besant Road,
Worli, Mumbai – 400018,
India.
Telephone: 91-22-6622 7575
Fax: 91-22-6622 7500 / 6622 7600

Manufacturer

S Kant Healthcare Ltd.
Plot No. 1802-1805, G.I.D.C. Phase III,
Vapi-396 195,
Gujarat, India
Tel : +91-260-6539518
Fax : +91-260-2430527
Email: regulatory@skant.com

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

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