

PATIENT COUNSELLING INFORMATION

^{Rx} Tinidazole and Diloxanide Furoate Tablets

Sprot[®]

Read the entire leaflet carefully before you start taking this medicine:

- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.

1. What is Sprot[®] and what is it used for?

Sprot[®] is a combination of two medicines: Tinidazole 300 mg and Diloxanide Furoate 250 mg. Tinidazole and Diloxanide Furoate are used to treat infections caused by micro-organisms like protozoa that cause amebiasis, giardiasis, etc.

Sprot Tablets[®] is indicated for the treatment of amebiasis and giardiasis.

You should ask your doctor if you are unsure why you have been given this medicine.

2. What you need to know before you take the Sprot[®]?

Do not take the Sprot[®]:

- You are allergic (hypersensitive) to Tinidazole, Diloxanide Furoate or any similar drugs. An allergic reaction could cause itching, a skin rash or wheezing. More severe symptoms include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing.
- You have a blood disorder or a history of blood disorders.
- You have central nervous system (CNS) disease, including epilepsy.
- You are in the first 13 weeks of pregnancy or trying to become pregnant or you are breast-feeding.

Warnings and precautions

Talk to your doctor, if abnormal neurological signs (such as, dizziness, vertigo, difficulty in controlling movements) develop during therapy with Sprot[®] as you may be told to stop your treatment.

Other medicines and Sprot®

Tell your doctor if you are taking or have recently taken any other medicines including those obtained without a prescription.

You should tell your doctor if you are currently taking blood thinners such as warfarin to prevent blood clots as your doctor may wish to monitor you more closely.

Sprot® with food and drink

You should not drink wine, beer or spirits during treatment and for 3 days after stopping treatment with this medicine. The combination may cause flushing, stomach cramps, vomiting (being sick) and palpitations (pounding heart).

Pregnancy and breast-feeding

If you are pregnant, planning to become pregnant or are breast-feeding, speak to your doctor before taking this medicine. It is important that you tell your doctor if you are breast-feeding as you may need a lower dosage of this medicine.

Driving and using machines

Do not drive or use machinery if this medicine makes you feel drowsy or gives you problems with co-ordination or sensation (e.g. numbness or weakness).

3. How to take the Sprot®?

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

Take Sprot® with a glass of water during or after a meal. Swallow the tablets whole. It is best to take the medicine at the same time each day.

If you take more tablets of the Sprot® than you should

If you accidentally take too much of this medicine tell your doctor or contact your nearest hospital casualty department immediately. Take any remaining tablets with you.

If you forget to take the Sprot®

If you forget to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking the Sprot®

If you stop taking this medicine too soon, the infection may return. Take this medicine for the full time of treatment, even when you begin to feel better.

If you have any further questions about the use of this medicine, ask your doctor for advice.

4. Possible side effects

Tinidazole:

Like all medicines, this medicine causes side effects, although not everybody gets them.

Tell your doctor immediately if you experience any of the following symptoms after taking this medicine.

Although they are very rare, the symptoms can be severe.

- Sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips or tongue
- Fits or seizures

The common side effects (that may affect up to 1 in 10 people) are listed below. These may go away during treatment as your body adjusts to the medicine. Tell your doctor if any of these side effects continue to bother you.

- Nausea (feeling sick) or vomiting, loss of appetite, diarrhoea, stomach pain or cramps
- Headache
- Vertigo
- Skin rash or itching (especially affecting the whole body).

The frequency of the following side effects is not known (cannot be estimated from the available data). You should contact your doctor if you notice any of the following:

- Numbness, tingling, pain or weakness in hands or feet
- Clumsiness or unsteadiness
- Fever or chills and painful ulcers in the mouth
- Sore or swollen mouth/tongue
- Redness of the face or neck
- Dizziness
- Tiredness
- Dark urine
- Tongue discolouration or unpleasant metallic taste.

Sprot[®] can sometimes cause a temporary reduction in white blood cells which does not usually give you any symptoms.

Diloxanide Furoate:

- Skin reddening, itching, difficulty in breathing or swelling. These could be signs of an allergic reaction and might not happen immediately-they may be experienced at the beginning of treatment or they may be delayed;
- Flatulence (wind)
- Feeling or being sick

- Diarrhoea
- Stomach pain
- Loss of appetite
- Headache
- Dizziness
- Skin rash

If you notice any side-effects mentioned above, please tell your doctor.

If any of the side-effects become severe, or if you notice any side-effects not listed in the leaflet please tell your doctor immediately.

5. How to store the Sprot[®]?

Do not take this medicine after the expiry date shown on the pack. The expiry date refers to the last day of that month.

Store protected from light and moisture.

Keep out of reach of children.

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