

PACKAGE LEAFLET: INFORMATION FOR THE USER

ZEPHOLIN S.R. 100 mg / 200 mg / 350 mg

Prolonged Release Capsules

(Theophylline)

Read all of this leaflet carefully before you start using this medicine.

- 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.

What is in this leaflet:

- 1. What Zepholin S.R. is and what it is used for**
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1. WHAT ZEPHOLIN S.R. IS AND WHAT IT IS USED FOR

Zepholin S.R. contains theophylline as the active ingredient which acts on your lung cells causing relaxation of the muscles. This makes your breathing easier and relieves breathlessness.

Zepholin S.R. is a prolonged release product which releases the theophylline slowly.

Zepholin S.R. is used:

- to treat asthma, chronic bronchitis and emphysema.

Zepholin S.R. can be taken both as a preventative therapy, to stop you getting breathing problems and as a therapy to relieve your breathlessness.

Zepholin S.R. should not be used as the first line treatment for asthma in children.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ZEPHOLIN S.R.

Do not take Zepholin S.R. if you:

- are allergic (hypersensitive) to theophylline or to any of the other ingredients of Zepholin S.R. prolonged release capsules. Please refer to section 6 of this leaflet for a list of all ingredients.
- are allergic (hypersensitive) to medicines from the xanthine group e.g. caffeine (in coffee or tea), aminophylline.
- have recently suffered a heart attack.
- have problems with the rhythm of your heart.
- are taking St. John's Wort (*Hypericum perforatum*).
- are pregnant or breast-feeding.

Zepholin S.R. should not be used in children under 6 months of age.

If you are not sure then talk to your doctor or pharmacist.

Warnings and Precautions with Zepholin S.R.

Speak to your doctor before taking Zepholin S.R. if you:

- have heart disease or any other heart problems
- have unstable angina
- have high blood pressure
- have an over active thyroid
- have stomach or duodenal ulcers
- have porphyria (a condition that affects the nervous system or skin, or both)
- have problems with your liver or kidneys

- consume excess alcohol
- suffer seizures
- have a fever
- have difficulty passing urine (especially in males)
- have insomnia (difficulty sleeping)
- are a smoker.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

If you are taking other medicines make sure your doctor is aware of them before you take Zepholin S.R., particularly if they are any of the following:

- medicines to treat heart conditions e.g. high blood pressure and angina (diltazem, verapamil, propranolol), irregular heart rate (propafenone, mexiletine), poor blood circulation (pentoifylline)
- medicines following a stroke e.g. ticlopidine
- other medicines for treating asthma, such as bronchodilators e.g. salbutamol, terbutaline, salmeterol or zileuton or zafirlukast
- medicines or products containing caffeine
- nonsteroidal anti-inflammatory cox2 drugs e.g. forecoxib
- medicines similar to Zepholin S.R. e.g. containing aminophylline or containing theophylline
- ephedrine (used in treatment of asthma and bronchitis and in antihistamines)
- medicines used to support the treatment of chronic alcoholism e.g. disulfiram
- oral contraceptives ("the pill")
- medicines for epilepsy such as phenobarbitone, carbamazepine, primidone or phenytoin
- antibiotics such as erythromycin, ciprofloxacin, fluoroquinolone, imipenem or rifampicin
- worming tablets containing thiabendazole
- stomach ulcer medicine containing cimetidine or ranitidine
- corticosteroids such as hydrocortisone or methyl prednisolone
- flu vaccines
- medicines to treat autoimmune conditions e.g. α interferon
- tuberculosis (TB) e.g. isoniazid
- anti virals e.g. ritonavir or aciclovir
- antidepressants e.g. fluvoxamine, viloxazine, lithium, benzodiazepines or barbiturates
- diuretics to increase urine production
- medicines for gout e.g. sulphapyrazone or allopurinol
- herbal preparations containing St. John's Wort (*Hypericum perforatum*)

If you are presently taking any of these medicines and are unsure talk to your doctor or pharmacist.

Children and adolescents

Zepholin S.R. should not be used in children under 6 months of age.

Zepholin capsules should not be used in children under 6 years of age. Other dosage forms are available that are more suitable for children aged less than 6 years.

Children over 6 years of age should only be treated with Zepholin S,R if no other suitable formulation is available. If treated, the dose is based according to their body weight with either Zepholin 100 mg or 200 mg.

Zepholin S.R. with food, drink and alcohol

Taking Zepholin S.R. with alcohol may affect how this medicine works. The capsules should be swallowed whole, after meals with plenty of fluid.

The daily dose should be divided between morning at breakfast and evening, shortly before bed. Please consult your doctor if you intend to drink alcohol while taking these capsules.

Pregnancy, breast-feeding and fertility

Do not take Zepholin S.R. if you are pregnant or breast-feeding unless it is considered essential by your physician.

Ask your doctor for advice before taking any medicine.

Driving and using machines

Taking Zepholin S.R. may affect your ability to drive or operate machinery. If you experience dizziness or blurred vision, do not drive or operate machinery. These affects may be enhanced if you take alcohol or others medicines with Zepholin S.R.

3. HOW TO TAKE ZEPHOLIN S.R

Always use Zepholin S.R. exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Zepholin S.R. is taken by mouth.
- They should be swallowed whole not chewed, with a glass of water.

Your doctor will carry out regular blood tests while you are taking this medicine. It is very important that you have these blood tests, especially if you are on high doses above 1000 mg daily.

Adults:

The dose in adults can vary but usually ranges from 300 mg to 450 mg twice daily. The dose might vary depending on blood test results.

Children:

Children under 6 years of age should not be treated with Zepholin S.R. Children from 6 years of age should be treated according to their body weight with Zepholin S.R. 100 mg or 200 mg.

Infants:

Infants under 6 months of age should not be treated with Zepholin S.R.

If you take more Zepholin S.R. than you should

If you take too much Zepholin S.R. or you feel unwell after taking Zepholin S.R., tell your doctor immediately or contact your nearest hospital casualty department.

If you forget to take Zepholin S.R.

If you forget to take a dose, take it as soon as you remember, but do not take a double dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Zepholin S.R. can cause side effects, although not everybody gets them.

At the first signs of a hypersensitivity reaction, stop taking Zepholin S.R. and tell your doctor.

Hypersensitivity reaction symptoms may include: swelling of the mouth, tongue, face and/or throat, breathing or swallowing difficulties (chest tightness or wheezing), hives, sudden fall in blood pressure leading to collapse or shock, which may be fatal.

Common side effects (may affect up to 1 in 10 patients):

- headache, nausea (feeling of sickness)

Uncommon side effects (may affect up to 1 in 100 patients):

- increased levels of uric acid in your blood, which may cause gout.
- hypersensitivity reactions
- tremor, seizures, dizziness, anxiety
- palpitations or rapid beating of the heart
- stomach reflux, vomiting
- increased need to or the inability to go to the toilet.

Not known (cannot be estimated from the available data):

- agitation, tremor, restlessness

- insomnia (unable to sleep)
- cramp
- low blood pressure
- irregular rhythm of the heartbeat

These effects are often mild and may wear off after a few days of treatment. If they are severe or last for more than a few days, tell your doctor. Your doctor may reduce the amount of Zepholin S.R. that you take to stop the unwanted effects.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ZEPHOLIN S.R.

Keep out of the sight and reach of children.

Do not store above 25°C. Do not use Zepholin S.R. after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Zepholin S.R. contains

The active substance is theophylline.

Each Prolonged Release capsules contains 100 mg, 200 mg or 350 mg of theophylline.

The other ingredients are Povidone, Colloidal Anhydrous Silica, Ammonio Methacrylate Copolymer Type A, Ammonio Methacrylate Copolymer Type B, Triethylcitrate, Talc and Gelatin. The gelatin capsule contains the following colours: Indigotine (E132), the 100 mg strength also contains Titanium Dioxide (E171) and the 200 mg and 350 mg strengths also contain Quinoline Yellow (E104). The capsule printing ink for the 100 mg strength contains Shellac Glaze, Iron Oxide Black (E172), Propylene Glycol E1520 and Ammonium hydroxide and the ink for the 200 mg and 350 mg strength contains Shellac, Propylene Glycol and Titanium Dioxide (E171).

What Zepholin S.R. looks like and contents of the pack

Zepholin S.R. 100 mg Prolonged Release Capsules are prolonged release hard gelatin capsules with a blue opaque cap and a white opaque body with "TH 100" in black print on both cap and body.

Zepholin S.R. 200 mg and 350 mg Prolonged Release Capsules are prolonged release hard gelatin capsules with a green cap and a transparent green body with "TH 200" or "TH 350" in white print on both cap and body.

The contents of the capsules are white pellets containing 100 mg or 200 mg or 350 mg of theophylline as a prolonged release medicine.

Zepholin S.R. are available only on prescription from your doctor in blister-packs of 56 capsules.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Astellas Pharma Co. Ltd. 5 Waterside, Citywest Business Campus,
Naas Road, Dublin 24, Ireland

Manufacturer:

Swiss Caps GmbH
Grassingerstraße 9
83043 Bad Aibling, Germany

For any information about this medicine, please contact the marketing authorization holder.

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Zepholin S.R. 100 mg Prolonged Release Capsules P.A. 1241/15/1

Zepholin S.R. 200 mg Prolonged Release Capsules P.A. 1241/15/2

Zepholin S.R. 350 mg Prolonged Release Capsules P.A. 1241/15/3