Package leaflet: Information for the user

Zostex 125 mg tablets

Brivudin

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 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 of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

[To be completed nationally]

What is in this leaflet:

1. What Zostex is and what it is used for

Zostex contains the active substance brivudin. Zostex has an antiviral effect and stops the virus that causes shingles (the varicella-zoster virus) from multiplying.

Zostex is used in adults with no abnormality of their immune system (the body's defences) for the early treatment of shingles (herpes zoster).

2. What you need to know before you take Zostex

Do <u>not</u> take Zostex

► if you are allergic (hypersensitive) to the active substance brivudin

► if you are allergic (hypersensitive) to any of the other ingredients of Zostex (see Section 6)

► if you are pregnant or breast-feeding

► if you are less than 18 years old.

In particular, do **NOT** take Zostex:

► if you are receiving medicines to treat cancer (chemotherapy), especially if you are being treated with:

- 5-fluorouracil (also called 5-FU, an active substance belonging to a group called 5-fluoropyrimidines)
- creams, ointments, eye drops or any other form of externally applied medicine that contains 5-fluorouracil
- active substances which are converted by the body into 5-fluorouracil such as:
  - capecitabine
  - floxuridine
  - tegafur
- any other active substance of the 5-fluoropyrimidine group
- combinations of any of the above mentioned active substances

► if your immune system (i.e. your body's defence against infections) is **severely** impaired; for example, if you are being treated with:

- cancer medicines (chemotherapy), or
- immunosuppressant medicines (i.e. medicines that suppress or diminish the function of your immune system)

► if you are being treated for a fungal infection with a medicine containing flucytosine

► if you are using a wart medicine containing an active substance of the 5-fluoropyrimidine group

Warnings and precautions

Talk to your doctor or pharmacist before taking Zostex.

Do not take Zostex together with medicines containing 5-FU or other 5-fluoropyrimidines (see sections "Do not take Zostex" and "Other medicines and Zostex").

Do not take Zostex if your **skin rash** is already fully developed (beginning of crusting). If you are unsure, ask your doctor.

Ask your doctor for advice before taking Zostex if you are suffering from **chronic diseases of the liver** (e.g. chronic hepatitis).

You should not take Zostex for more than 7 days, because extending treatment over the recommended duration of 7 days increases the risk of developing hepatitis (see also section 4).

Children and adolescents

Do not give Zostex to children and adolescents between 0 to 18 years, since the safety and efficacy in this age group have not been studied.

Other medicines and Zostex

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines, including medicines obtained without a prescription.

PLEASE NOTE:

Special warning for patients receiving therapy with products containing 5-fluorouracil or other 5-fluoropyrimidines (see also the red box above):

Zostex must **not** be used together with any cancer chemotherapy medicine which contains one of the following active substances, as the harmful effects of these medicines could be strongly increased and may be fatal:
► 5-fluorouracil, including forms to be used locally
► capecitabine
► floxuridine
► tegafur
► other 5-fluoropyrimidines
► combinations of any of the above mentioned substances with other active substances.

Do not take Zostex together with medicines containing the active substance flucytosine used to treat fungal infections.

Do not take Zostex and contact your doctor immediately if you:
► are receiving therapy with any of the above medicines
► will be receiving therapy with any of the above medicines within 4 weeks of the end of treatment with Zostex.

If you have accidentally used Zostex and one of the medicines listed above:
► stop taking both medicines
► consult a doctor immediately.
You may need to go to the hospital for treatment.

Symptoms and signs of 5-fluorouracil toxicity due to the above interactions include:
► feeling sick; diarrhoea; inflammation of the mouth and/or inner lining of the mouth; decreased white blood cell count and depressed bone marrow function; flat red rash all over the body, with skin becoming painful to touch, followed by large blisters leading to extensive areas of peeling skin (toxic epidermal necrolysis) (see also sect. 4).

Post-marketing experience indicates a possible interaction of brivudin with anti-Parkinson dopaminergic drugs, that may facilitate the onset of chorea (abnormal, involuntary, dance-like movements, especially of arms, legs and face).

Zostex with food and drink

You may take Zostex with or without food.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before using any medicine.

Do not use Zostex during pregnancy.

Do not use Zostex if you are breast-feeding. The active substance of Zostex may be passed onto your baby through your breast milk.

Driving and using machines

Although uncommon, dizziness and sleepiness have been experienced by a few patients taking Zostex. If you notice such side effects, do not drive or use machines or work without a secure foothold. Ask your doctor for advice.

Zostex contains lactose

This medicine contains milk sugar (lactose). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Zostex

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

The recommended dose is:

1 Zostex 125 mg tablet once a day for 7 days.

Take your Zostex tablet at about the same time each day.

You may take Zostex with or without food.

Swallow the tablet whole with enough liquid, e.g. a glass of water.

You should start treatment **as early as possible**. This means that if possible you should start taking Zostex:
► within 3 days of the appearance of the first skin signs of shingles (skin rash) or
► within 2 days of the appearance of the first blisters.

Complete the 7-day treatment cycle even if you get better earlier.

If your symptoms persist or get worse during your week of treatment you should see your doctor.

Taking the usual dose of Zostex reduces the risk of developing postherpetic neuralgia in patients over 50 years of age. Postherpetic neuralgia is persistent pain that develops in the area where you suffered shingles, after the rash has got better.

Duration of treatment

This medicine is for short-term use. It should be taken for 7 days only. Do not take a second course of treatment.

Use in children and adolescents

Do not take Zostex if you are under 18 years of age.

If you take more Zostex tablets than you should

If you take more tablets than you should, please inform a doctor. He will decide whether further measures are necessary.

If you forget to take Zostex

If you forget to take your tablet at the usual time, take it as soon as you remember. Take the next tablet on the next day at about the same time as the previous day. Continue with this new dose timing until you complete the 7 day course of treatment.

Do not take a double dose to make up for a forgotten tablet.

Tell your doctor if you repeatedly miss your daily dose.

If you stop taking Zostex

Do not stop taking Zostex without first talking to your doctor. To gain the full benefit of this treatment, you must take it for 7 days.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Stop taking Zostex and tell your doctor straight away if you have an allergic reaction with signs and symptoms including skin itchiness or reddening (rash), increased sweating, swelling (of hands, feet, face, tongue, lips, eyelids, or voicebox), difficulty in breathing (see also sect. 4). These symptoms may be serious and require urgent medical attention.

The following side effect was commonly observed (may affect up to 1 in 10 people):

► nausea (feeling sick).

The following side effects were uncommonly observed (may affect up to 1 in 100 people):

► a fall in the number of a type of white blood cells (granulocytes)
► a rise in the number of certain types of white blood cells (eosinophils, lymphocytes, monocytes)
► a fall in the number of red blood cells (anaemia)
► allergic reactions including:
- itchiness of the skin (pruritus)
- redness of the skin (erythematous rash)
- increased sweating
- swelling of: hands, feet, face, tongue, lips, eyelids, voice box (laryngeal oedema)
- cough**,** difficulty in breathing and/or shortness of breath

► lack of appetite
► anxiety
► sleeplessness (insomnia), sleepiness (somnolence)
► headache
► dizziness
► vertigo (a sensation of spinning)
► abnormal sensation, e.g. burning, prickling, tingling, sensation of pins and needles, most frequently in the arms and legs (paraesthesia)
► increased blood pressure
► indigestion (dyspepsia), vomiting, stomach ache
► diarrhoea
► excessive gas in the stomach or bowel (flatulence)
► constipation
► chronic liver disease with fat accumulation (fatty liver)
► increase in the blood levels of certain substances produced by the liver (raised liver enzymes)
► weakness, tiredness (fatigue)
► flu-like symptoms (malaise, fever, body aches and chills)

The following side effects were rarely observed (may affect up to 1 in 1000 people):

► low blood pressure
► reduction in the number of platelets in the blood
► hallucinations, delusions
► confusional state
► tremor
► altered sense of taste
► ear pain
► inflammation of the liver (hepatitis)**,** increased blood bilirubin
► bone pain

The following have also been reported, however their frequency is not known (frequency cannot be estimated from available data):

► disequilibrium
► inflammation of blood vessels (vasculitis)

- rapid-onset liver failure
- a localized skin inflammation that recurs in the same place over a period of time (fixed eruption), skin inflammation with peeling (exfoliative dermatitis), serious whole-body rash on skin and inside of mouth, due to an allergic reaction (erythema multiforme), ulceration of the skin, mouth, eyes and genital areas (Stevens Johnson syndrome).

Reporting of side effects

If you get any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zostex

Keep out of the reach and sight of children.

Do not use this medicine after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.

Keep the blister strip in the outer carton in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Zostex contains

The active substance is brivudin.

1 tablet of Zostex contains 125 mg brivudin.

The other ingredients are:
- microcrystalline cellulose
- lactose monohydrate
- povidone K 24-27
- magnesium stearate.

What Zostex looks like and contents of the pack

Zostex 125 mg tablets are round, flat, white or almost white, and have a bevelled (angled) edges.

They are provided in a blister pack packed into a carton.

Zostex is available in packs containing 1 and 7 tablets and in multipacks comprising 5 cartons, each containing 7 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

Germany	Zostex, Zostex, Menavir
Austria	Mevir, Zostex
Belgium	Zerpex, Zonavir
Croatia	Brivuzost
Czech Republic	Zostevir
Estonia	Brivumen
Greece	Brivir, Zostevir
Italy	Brivirac, Viruselect, Zecovir
Lithuania	Brivumen
Luxembourg	Zerpex, Zonavir
Portugal	Bridic, Zostex
Romania	Brival
Slovakia	Zovudex
Slovenia	Zostex
Spain	Nervinex

This leaflet was last revised in ..... [To be completed nationally]