Package leaflet:
Information for the patient

pentosan polysulfate sodium bene-Arzneimittel GmbH 100 mg capsules, hard

pentosan polysulfate sodium

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 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 pentosan polysulfate sodium is and what it is used for
2. What you need to know before you take pentosan polysulfate sodium
3. How to take pentosan polysulfate sodium
4. Possible side effects
5. How to store pentosan polysulfate sodium
6. Contents of the pack and other information

1. What pentosan polysulfate sodium is and what it is used for

This medicine contains the active substance pentosan polysulfate sodium. After taking the medicine, it passes into the urine and attaches to the lining of the bladder, helping to form a protective layer.

pentosan polysulfate sodium is used in adults to treat **bladder pain syndrome** characterised by many tiny bleeds or distinctive lesions on the bladder wall and moderate to severe pain and a frequent urge to urinate.

2. What you need to know before you take pentosan polysulfate sodium

Do not take pentosan polysulfate sodium if you are
- **allergic** to pentosan polysulfate sodium or any of the other ingredients of this medicine (listed in section 6)
- **bleeding** (other than menstrual bleeding)

Warnings and precautions

Talk to your doctor or pharmacist before taking pentosan polysulfate sodium if you have:
- to undergo surgery
- a blood clotting disorder or increased risks of bleeding, such as using a medicine that inhibits blood clotting
- ever had a reduced number of blood platelets caused by the medicine called heparin
- reduced liver or kidney function

Rare cases of retinal disorders (pigmentary maculopathy) have been reported with use of pentosan polysulfate sodium (especially after long term use). Tell your doctor immediately if you experience visual changes such as difficulty when reading, visual distortions, altered colour vision and/or slower adjustment to low or reduced light. Your doctor will discuss with you whether the treatment should be continued. For early detection of retinal disorders, eye examination will be performed regularly.

Children and adolescents

pentosan polysulfate sodium **is not recommended** in children under 18 years as safety and efficacy have not been established in this group.

Other medicines and pentosan polysulfate sodium

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Inform your doctor or pharmacist, particularly if you use medicines that prevent blood clotting, or painkillers that reduce blood clotting.

Pregnancy and breast-feeding

pentosan polysulfate sodium **is not recommended** during pregnancy or breast-feeding.

Driving and using machines

pentosan polysulfate sodium has no or negligible influence on the ability to drive and use machines.

pentosan polysulfate contains sodium.

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take pentosan polysulfate sodium

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

The recommended dose is:

1 capsule, 3 times daily
Your doctor will assess your response to pentosan polysulfate sodium every 6 months.

Method of use

Take the capsules whole with one glass of water, at least 1 hour before or 2 hours after meals.

If you take more pentosan polysulfate sodium than you should

Inform your doctor in case of overdose.
Stop taking pentosan polysulfate sodium if side effects occur until they disappear.

If you forget to take pentosan polysulfate sodium

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

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.

Side effects have been observed with the following frequencies:

Common: may affect up to 1 in 10 people
- infections, flu
- headache, back pain
- dizziness
- nausea, indigestion, diarrhoea, abdominal pain, abdomen enlarged
- rectal bleeding
- accumulation of fluid in arms or legs
- hair loss
- weakness, pelvic (lower abdomen) pain
- need to urinate more frequently than usual
- abnormal liver function

Uncommon: may affect up to 1 in 100 people
- lack of blood platelets, red or white blood cells
- bleeding, including small bleeding beneath the skin
- allergic reactions, increased sensitivity to light
- loss of appetite, weight gain or loss
- severe mood swings or depression
- increased sweating, sleeplessness
- restlessness
- abnormal sensation such as prickling, tingling and itchiness
- flow of tears, lazy eye
- ringing or buzzing in the ears
- breathing difficulties
- indigestion, vomiting, wind, difficulty passing stools
- mouth ulcer
- skin rash, increased mole size
- joint or muscle pain

Not known: frequency cannot be estimated from the available data
- blood clotting disorders
- allergic reactions
- abnormal liver function

Reporting of side effects

If you get any 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
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard
or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store pentosan polysulfate sodium

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

- **bottle**

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

Keep the bottle tightly closed in order to protect from moisture.
After first opening: use within 45 days.
Dispose any remaining capsules after this period.

Do not throw away any medicines via wastewater. Ask your pharmacist 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 this medicine contains
- The active substance is pentosan polysulfate sodium.
  One capsule contains 100 mg pentosan polysulfate sodium.
- The other ingredients are:
  Capsule content: microcrystalline cellulose, magnesium stearate
  Capsule shell: gelatin, titanium dioxide (E171)

What pentosan polysulfate sodium looks like and contents of the pack

The capsules are white and non-transparent, provided in a plastic bottle with child resistant closure, packed in a carton.
Each carton contains 90 capsules.

Marketing Authorisation Holder and Manufacturer

bene-Arzneimittel GmbH
Herterichstr. 1-3
81479 Munich
Germany
tel: +49 (0)89 749870
e-mail: contact@bene-gmbh.de

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

United Kingdom
Consilient Health Limited
Tel: +44 (0)20 3751 1888

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