Interstitial cystitis: oral pentosan polysulfate sodium

Information for the public
Published: 21 April 2015
nice.org.uk

About this information

This information explains the evidence summary about the unlicensed use of oral pentosan polysulfate sodium (pentosan) for interstitial cystitis, also known as chronic pelvic pain syndrome or bladder pain syndrome. The evidence summary is an overview of the available information about this medicine. It aims to help prescribers and patients when they are considering whether or not to use an unlicensed or off-label treatment. The summary does not contain recommendations from NICE on whether the medicine should be used.

Licensing medicines

In the UK, medicines need to have a licence before they can be marketed. To get a licence, the manufacturer of the medicine has to provide evidence that shows that the medicine works well enough and is safe enough to be used for a specific condition and for a specific group of patients, and that they can manufacture the medicine to the required quality. Medicines can be prescribed without a licence (an 'unlicensed medicine') if there is no suitable licensed alternative and it is likely to benefit the patient.

A medicine can also be prescribed 'off-label'. This means the prescriber wants to use it in a different way than is set out in the terms of its licence. This could mean using the medicine for a different condition or a different group of patients, or it could mean a change in the dose or that the medicine is taken in a different way. There is more information about licensing medicines on NHS Choices.
What is interstitial cystitis?

Interstitial cystitis, which may also be called chronic pelvic pain syndrome or bladder pain syndrome, is a long-term condition with pain in the bladder and pelvis. There may be pain when the bladder is full or when passing urine, a strong need to urinate and needing to urinate often. The condition can have a big effect on a person's life because of the need to visit the toilet frequently, both during the day and at night. It is not known what causes interstitial cystitis, and the diagnosis is usually made when other causes of the symptoms have been ruled out.

About pentosan

Pentosan polysulfate sodium (pentosan) is used to treat the symptoms of interstitial cystitis and is taken by mouth (this is known as 'oral').

Pentosan is not licensed in the UK, so its use for interstitial cystitis is unlicensed.

There is no single treatment for interstitial cystitis. Treatment options include exercises to strengthen the muscles of the pelvic floor, programmes to train the bladder, avoiding food and drink that trigger the problem, other oral medicines, medicines that are introduced directly into the bladder, and surgery. The choice of treatment will depend on the individual person and their symptoms.

Summary of possible benefits and harms

How well does pentosan work?

Five studies have looked at how well pentosan works for treating interstitial cystitis in adults, compared with placebo (a dummy tablet).

The most recent and largest study suggested that pentosan was no better than a dummy tablet at reducing pain or improving other symptoms of interstitial cystitis.

The other 4 older studies (from the 1980s and 1990s) when looked at all together, suggested that pentosan was better than the dummy tablet at relieving pain, reducing how often people needed to urinate and how urgently. One of the studies also asked about the number of times people woke to pass urine at night, and found that pentosan was no better than the dummy tablet at reducing this symptom.
There are no good quality studies comparing pentosan with other treatments used for interstitial cystitis.

**What are the possible harms or side effects?**

In the studies, the most common side effects of pentosan were headache, feeling sick, diarrhoea, skin rash and hair loss (alopecia).

Pentosan is a type of anticoagulant (a drug that thins the blood). It is described as a 'weak anticoagulant' and doesn't usually cause bleeding. However, people who are taking other medicines to thin their blood, who are due to have surgery, or who have a condition that may mean they bleed more easily, should speak to their doctor before taking pentosan.

Please note that the results of the research studies only indicate the benefits and harms for the population in the studies. It is not possible to predict what the benefits and harms will be for an individual patient being treated with pentosan.

**Prescribing pentosan**

If a prescriber wants to use an unlicensed or off-label medicine, they must follow their professional guide, for example for doctors the General Medical Council’s good practice guidelines. These include giving information about the treatment and discussing the possible benefits and harms so that the patient has enough information to decide whether or not to have the treatment. This is called giving informed consent.

A full version of the summary aimed at healthcare professionals is available on the NICE website. The summary for healthcare professionals does not contain recommendations from NICE on whether the medicine should be used.

**Questions to ask**

- Why am I being offered an unlicensed medicine?
- What does the treatment involve?
- What are the benefits I might get?
- How good are my chances of getting those benefits?
• Could having the treatment make me feel worse?

• Are there alternative treatments?

• What are the risks of the treatment?

• Are the risks minor or serious? How likely are they to happen?

• What may happen if I don't have the treatment?

More information

NICE has published information about how evidence summaries for unlicensed and off-label medicines are developed.

Copyright

© National Institute for Health and Care Excellence 2015. All rights reserved. NICE copyright material can be downloaded for private research and study, and may be reproduced for educational and not-for-profit purposes. No reproduction by or for commercial organisations, or for commercial purposes, is allowed without the written permission of NICE.

ISBN: 978-1-4731-1168-4