Package Leaflet: Information for the user

PROSTAP® PD DCS
1.88 mg Powder and Solvent for Prolonged-release Suspension for Injection in Pre-filled Syringe

leuprorelin acetate

Read all of this leaflet carefully before your child is given 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 nurse.
- This medicine has been prescribed for your child. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If your child gets any side effects talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- PROSTAP PD DCS 1.88mg powder & solvent forprolonged-release suspension for injection in pre-filledsyringe will be referred to as Prostap PD DCS throughout the remainder of this leaflet.

What is in this leaflet:

1. What PROSTAP PD DCS is and what it is used for
2. What you need to know before your child is given PROSTAP PD DCS
3. How to use PROSTAP PD DCS
4. Possible side effects
5. How to store PROSTAP PD DCS
6. Contents of the pack and other information

1. WHAT PROSTAP PD DCS IS AND WHAT IT IS USED FOR

PROSTAP PD DCS is a synthetic hormone which can be used to reduce the levels of testosterone and oestrogen (sex steroids) circulating in the body.

PROSTAP PD DCS is used to treat premature puberty which is caused by a release of certain hormones from the pituitary gland (central precocious puberty) in girls under 9 years of age and boys under 10 years of age with a body weight of less than 20 kg. Your doctor will make a precise diagnosis of central precocious puberty.

2. WHAT YOU NEED TO KNOW BEFORE YOUR CHILD IS GIVEN PROSTAP PD DCS

Do not use PROSTAP PD DCS:

- If your child is allergic (hypersensitive) to leuprorelin or any of the other ingredients of PROSTAP PD DCS (listed in section 6).

- In girls with central precocious puberty
  - if the girl to be treated is pregnant or breast-feeding.
  - if the girl has abnormal vaginal bleeding which has not been discussed with her doctor (see Warnings and Precautions section below).

Warnings and Precautions:

When your child begins treatment with PROSTAP PD DCS, existing symptoms may initially get worse as a result of levels of sex steroids in the body increasing. These worsening symptoms usually subside with continued use of PROSTAP PD DCS (see section 4 for further information).

Severe skin rashes including Stevens-Johnson syndrome, Toxic Epidermal Necrolysis (SJS/TEN) have been reported in association with leuprorelin. Stop using leuprorelin and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Talk to your doctor or nurse before your child is given PROSTAP PD DCS:

- If your child has a seizure (fit), tell your doctor. There have been reports of seizures in patients receiving PROSTAP PD DCS. These occurred in patients with or without epilepsy or other reasons that increase the risk of having seizures.

- If your child develops depressed mood, tell your doctor. There have been reports of depression in patients receiving PROSTAP PD DCS, which may be severe.

- In the event of a sterile abscess at the injection site (mostly reported after injection into the muscle) your doctor will monitor hormone levels as there could be reduced absorption of leuprorelin from the injection site.

- Often sterile abscesses at the injection site occurred when PROSTAP PD DCS is administered in higher dosages than recommended and when it is administered into the muscle. Your doctor will therefore administer the medicinal product under the skin of e.g. abdomen, bottom or thigh.

- If your child has a progressive brain tumour, the doctor will decide if treatment with leuprorelin is appropriate.

- Bone density may decrease during treatment of central precocious puberty with PROSTAP PD DCS. However, after treatment is stopped, subsequent bone mass growth is preserved and peak bone mass in late adolescence does not seem to be affected by treatment.

- If your child suffers from a bad or recurrent headache, problems with their eyesight and ringing or buzzing in the ears contact your doctor immediately.

- If you have a fatty liver.

In girls with central precocious puberty:
- After the first injection vaginal bleeding (spotting) and discharge may occur as a sign of hormone withdrawal. Vaginal bleeding beyond the first/second month of treatment **needs to be investigated.**

- Discontinuation of treatment may lead to a slipping of the growth plate of the thigh bone. A possible cause could be a weakness of the growth plate due to a lower concentration of female sexual hormones during treatment.

Other medicines and PROSTAP PD DCS

Please tell your doctor or pharmacist if your child is taking or has recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

PROSTAP PD DCS must not be given to pregnant or breast-feeding girls (see also section "Do not use PROSTAP PD DCS').

Driving and using machines

Your child may feel dizzy, have blurred vision or difficulty focussing his/her eyes. If these happen it may be dangerous to do things such as use machines, ride a bike or a horse or climb trees.

PROSTAP PD DCS contains sodium

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

3. HOW TO USE PROSTAP PD DCS

Your doctor or nurse will give your child an injection of PROSTAP PD DCS. The injection should be given immediately after it has been prepared. The injection will normally be given in the arm, thigh or abdomen. The injection site should be varied at regular intervals.

Your child will normally be given an injection once a month.

The dosing scheme needs to be adapted individually.

The recommended starting dose is dependent on body weight:

a) <u>Children with a body weight less than 20 kg</u>
Taking into account the clinical activity of the central precocious puberty in these rare cases, the following applies:

Unless prescribed otherwise, 1 ml PROSTAP PD DCS (1.88 mg leuprorelin acetate) is administered once a month under the skin of e.g. abdomen, bottom or thigh as a single injection. Your doctor will monitor your child's weight gain.

b) Children with a body weight 20 kg or more
Other forms of leuprorelin may be more suitable, such as 1 ml PROSTAP SR (3.75 mg leuprorelin acetate) administered once a month under the skin.
Depending on the central precocious puberty activity, your doctor may increase the dosage in the presence of inadequate suppression (e.g. vaginal bleeding). Your doctor will determine the minimal effective dose with the help of a blood test.

The duration of treatment depends on the clinical signs at the start of treatment or during the course of treatment and may be decided by your doctor together with the legal guardian and, if appropriate, child being treated. Your doctor will determine the bone age of your child at regular intervals.

In girls with bone age of older than 12 years and boys with bone age of older than 13 years your doctor will consider discontinuing the treatment, depending on the clinical effects.

In girls, pregnancy should be excluded before the start of treatment. The occurrence of pregnancy during treatment cannot be generally excluded. In such cases, please talk to your doctor.

The therapy is a long-term treatment, adjusted individually. Please arrange with your doctor that PROSTAP PD DCS is administered as precisely as possible in regular monthly periods. An exceptional delay of the injection date for a few days (30 ± 2 days) does not influence the result of the therapy.

If you miss an injection

As soon as you realise your child has missed an injection, contact your doctor who will be able to give your child the next injection.

If you stop using PROSTAP PD DCS

Your doctor will talk to you and your child before stopping treatment.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, PROSTAP PD DCS can cause side effects, although not everybody gets them.

Contact your doctor immediately or go to hospital:

- If your child develops a severe rash, itching or shortness of breath or difficulty breathing. These could be symptoms of a severe allergic reaction.

Tell your doctor:

- If your child gets a severe headache which does not get better when they take painkillers.

At the beginning of treatment, a temporary rise in the sex hormone levels occurs, followed by a fall to values within the prepuberty range. Due to this effect, side effects may occur particularly at the start of treatment.

Common (may affect up to 1 in 10 people):

- mood swings
- depression
- headache
- abdominal pain/abdominal cramps
- feeling sick/vomiting
- acne
- vaginal bleeding
- vaginal spotting
- vaginal discharge
- injection site reactions (these include hardening, redness, pain, abscesses, swelling, nodules, ulcers and skin damage)

Uncommon (may affect up to 1 in 100 people):

- muscle ache

Very rare (may affect up to 1 in 10,000 people):

- general allergic reactions (symptoms include fever, rash, itching, wheals or chills)
- serious allergic reaction which causes difficulty in breathing or dizziness. If this happens, contact your doctor immediately or go to the hospital.
- in patients with existing tumours of the pituitary gland, bleeding of the pituitary gland may occur.

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

- seizure
- inflammation of lungs or lung disease
- idiopathic intracranial hypertension (increased intracranial pressure around the brain characterised by headache, double vision and other visual symptoms and ringing or buzzing in one or both ears).
- If you experience reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome/Toxic Epidermal Necrolysis).
- **Skin redness and itchy rash. (Toxic skin eruption)**
  A skin reaction that causes red spots or patches on the skin, that may look like a target or "bulls-eye" with a dark red centre surrounded by paler red rings (Erythema Multiforme).

In general, if vaginal bleeding (spotting) occurs with continued treatment (after possible withdrawal bleeding in the first month of treatment), this may be a sign of potential underdosage. Please tell your doctor if vaginal bleeding occurs.

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 the 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 PROSTAP PD DCS

Keep out of the sight and reach of children.

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

Do not refrigerate or freeze.

Store in the original container in order to protect from light.

Once mixed with the Sterile Solvent, the suspension must be used immediately.

If the pack has been opened or damaged, return it to your pharmacist.

Do not throw away any medicines via wastewater or household waste. 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 PROSTAP PD DCS contains:

- The active ingredient in PROSTAP PD DCS powder is leuprorelin acetate (1.88 mg).
- The other ingredients in PROSTAP PD DCS powder are: copolymer (DL-lactic acid/glycolic acid)and mannitol (E421).
- The Solvent contains carmellose sodium, mannitol (E421), polysorbate 80, water for injections and acetic acid, glacial.

What PROSTAP PD DCS looks like and contents of the pack:

PROSTAP PD DCS should only be administered by your doctor or a nurse who will also take care of the preparation of the product.

PROSTAP PD DCS is a prolonged release powder for use in an injection.

The solventis a clear liquid, which is mixed with the PROSTAP PD DCS Powder before injection.

Each pack contains a pre-filled dual chamber syringe containing 1.88 mg leuprorelin acetate powder in the front chamber and 1 ml of solvent in the rear chamber, a syringe needle fitted with a safety device and one syringe plunger.

Marketing Authorisation Holder:

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This leaflet does not contain the complete information about your medicine. If you have any questions or you are not sure about anything you should ask your doctor or nurse who can give you more information. The information in this leaflet applies only to PROSTAP PD DCS.

This leaflet was last revised in June 2024.

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