

Package leaflet: Information for the user

Betnesol 4mg/mL Solution for Injection

Betamethasone sodium phosphate

- **Betnesol Injection is a steroid medicine**, prescribed for many different conditions, including serious illnesses.
- **You need to use it regularly** to get the maximum benefit.
- **Don't stop using this medicine** without talking to your doctor - you may need to reduce the dose gradually.
- **Betnesol Injection can cause side effects in some people** (see section 4). Some problems such as mood changes (feeling depressed or 'high') or stomach problems can happen straight away. If you feel unwell in any way, keep using your medicine but **see your doctor straight away**.
- **Some side effects only happen after weeks or months**. These include weakness of arms and legs or developing a rounder face (see section 4).
- **If you use it for more than 3 weeks, you will get a blue 'steroid card'**: always keep it with you and show it to any doctor or nurse treating you.
- **Keep away from people who have chickenpox or shingles**, if you have never had them. They could affect you severely. If you do come into contact with chickenpox or shingles, **see your doctor straight away**.

Read all of this leaflet carefully before you are 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.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet Betnesol 4mg/mL Solution for Injection will be called Betnesol Injection.

What is in this leaflet

1. What Betnesol Injection is and what it is used for
2. What you need to know before you are given Betnesol Injection
3. How you will be given Betnesol Injection
4. Possible side effects
5. How to store Betnesol Injection
6. Contents of the pack and other information

1. What Betnesol Injection is and what it is used for

Betnesol Injection belongs to a group of medicines called steroids. Their full name is corticosteroids.

These corticosteroids occur naturally in the body and help to maintain health and well being. Boosting your body with extra corticosteroids (such as Betnesol Injection) is an effective way to treat various illnesses involving inflammation in the body. Betnesol Injection reduces this inflammation, which could otherwise go on making your condition worse. You must use this medicine regularly to get maximum benefit from it.

Many different conditions can be improved by the use of corticosteroids, as they reduce inflammation (redness, tenderness, heat and swelling) in the body.

Betnesol Injection is used:

- to treat asthma
- to treat severe allergic reactions including reactions to drugs
- to treat local inflammation e.g. of joints, tendons or the eye
- as replacement for the body's naturally occurring corticosteroid hormones when these are reduced or absent
- to treat severe shock, (collapse) due to surgery, injury or overwhelming infection.

Corticosteroids are also used to help prevent organ transplant rejection following organ transplant surgery.

2. What you need to know before you are given Betnesol Injection

Do not use Betnesol Injection:

- if you are allergic to betamethasone or any of the other ingredients of this medicine (listed in section 6)
- if you have an infection and have not yet started taking any medicine (e.g. antibiotics) to treat it.

Warnings and precautions

Talk to your doctor or nurse before you are given Betnesol Injection

- If you have ever had severe depression or manic depression (bipolar disorder). This includes having had depression before while using steroid medicines like Betnesol Injection
- If any of your close family has had these illnesses
- If you have or have ever had tuberculosis (TB)
- If you have epilepsy (fits), severe mental illness, heart disease, hypertension (high blood pressure), stomach or duodenal ulcers, diverticulitis (inflammation of the bowel) or a herpes infection of the eye
- If you have osteoporosis (thinning of the bones). Post menopausal women are particularly at risk of this.
- If you or any of your family have ever had glaucoma (raised eye pressure)
- If you have recently had a heart attack
- If you have had a stroke or if there is a history of stroke in your family

- If you have recently had a head injury
- If you have recently been in contact with someone who has chickenpox, shingles or measles or recently had chickenpox, shingles or measles yourself. This product may make chickenpox, shingles or measles much worse.
- If you or any of your family are diabetic
- If you have an underactive thyroid gland
- If you have myasthenia gravis (a disease which causes muscle weakness)
- If you have ever suffered from muscle wasting due to corticosteroids
- If you have liver, kidney or heart disease
- If you have just been or are about to be immunised
- If you have an infection
- If you are pregnant or breast-feeding (see “Pregnancy and breast-feeding” section below).

Other medicines and Betnesol Injection

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

- Some medicines may increase the effects of Betnesol Injection and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat)
- Insulin or oral antidiabetic drugs
- Medicines for high blood pressure
- Water tablets (diuretics)
- Medicines for thinning the blood e.g. warfarin
- Non-steroidal anti-inflammatory drugs e.g. ibuprofen
- Salicylates e.g. aspirin
- Medicines for myasthenia gravis called anticholinesterases
- Medicines for the heart called cardiac glycosides
- Acetazolamide (used to treat glaucoma)
- Rifampicin and rifabutin (antibiotics for tuberculosis) and ephedrine
- Carbamazepine, phenytoin, primidone, phenobarbitone and aminoglutethimide for epilepsy
- Carbenoxolone (an ulcer healing drug), theophylline (used to treat asthma and other breathing difficulties) and amphotericin B (anti-fungal)
- Oral contraceptives (the pill)
- Mifepristone (anti-progesterone)
- Somatropin (growth hormone)
- Vecuronium and other muscle relaxants
- Fluoroquinolones (used for some infections)
- Quetiapine (improves symptoms of some mental illnesses)
- Tretinoin (used for skin problems such as bad acne)
- Any other medicine, including medicines obtained without a prescription.

Betnesol Injection may also affect the results of gall-bladder X-ray procedures.

Mental problems while using Betnesol Injection

Mental health problems can happen while using steroids like Betnesol Injection (see section 4).

- These illnesses can be serious
 - Usually they start within a few days or weeks of starting the medicine
 - They are more likely to happen at high doses
 - Most of these problems go away if the dose is lowered or the medicine is stopped.
- However, if problems do occur they may need treatment.

Talk to a doctor if you (or someone who is using this medicine), shows any signs of mental problems. This is particularly important if you are depressed or might be thinking about suicide. In a few cases, mental problems have happened when doses are being lowered or stopped.

Chickenpox, shingles or measles

You should avoid contact with anyone who has either chickenpox, shingles or measles as it could be extremely serious if you caught any of these from them.

Tell your doctor immediately if you suspect you may have come into contact with a person who has chickenpox, shingles or measles. However do not stop using this medicine, unless your doctor tells you to.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

Pregnancy:

Taking steroids often or for a long period of time during pregnancy, can slow the baby's growth in the womb or may temporarily affect the baby's heart and body movements. Sometimes the baby may get digestive juices going up into the tube that carries food from the mouth to the stomach. The baby may also make less of its own steroid after birth but this rarely causes any problems. If you become pregnant whilst using this medicine, please tell your doctor but **DO NOT stop treatment unless told to do so** (see section 3).

Breast-feeding:

If you are breast-feeding, the steroid may enter the baby and lower their hormone levels if you are using high doses for a long period of time.

Betnesol Injection contains sodium metabisulphite and sodium

Betnesol Injection contains sodium metabisulphite (0.1% w/v) as a preservative, it may rarely cause severe hypersensitivity reactions and bronchospasm. This medicinal product contains less than 1 mmol sodium (23 mg) per 1ml, i.e. essentially 'sodium-free'. Tell your doctor or nurse before you are given Betnesol Injection if this applies to you.

3. How you will be given Betnesol Injection

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

Important: Your doctor will choose the dose that is right for you.

You may have been given a steroid card which also tells you how many injections you need each day (see section 6).

The dose used will depend upon the disease, its severity and how quickly you get better. Betnesol Injection is not intended for long term use. The following are for guidance only:

The recommended doses are:

Local injections (excluding eye):

Adults: 4 – 8mg (1 – 2ml), repeated up to 3 times.

Use in children and adolescents:

Children may have a smaller dose

Eye injections:

Adults and children: 2 – 4mg (0.5 – 1ml)

Other injections: Adults: 4 – 20mg (1 – 5ml)

Use in children and adolescents:

Children 6 – 12 years: 4mg (1ml)

Children 1 – 5 years: 2 mg (0.5ml)

Children up to 1 year: 1mg (0.25ml)

These doses can be repeated up to 4 times a day.

If you have any queries about the amount of medicine you have been prescribed, ask your doctor.

While you are using this medicine, your doctor may ask you to have check-ups. These are to make sure that your medicine is working properly and that the dose you are taking is right for you.

Method of administration:

Betnesol Injection can be given slowly into a vein, deep into a muscle or locally at the site of inflammation. It should not be injected directly into tendons. Your doctor will decide where, how much and how often you should be given Betnesol Injection.

If you are given more Betnesol Injection than you should

If you think you have been given too much of the injection, immediately tell your doctor or nurse. The dose may be reduced slowly over time to minimise any effects.

If you forget to use Betnesol Injection

If you forget to have a dose, i.e. miss your doctor's appointment; see your doctor as soon as possible.

If you stop using Betnesol Injection

Do not stop using Betnesol Injection without first talking to your doctor.

It is very important that you do not suddenly stop using Betnesol Injection, even if you feel better from your original illness or are suffering from a side-effect unless your doctor tells you to. If you stop using your medicine too suddenly, you may suffer from some of the following: fever, joint and muscle pain, itchy eyes, nose or skin, mood changes, loss of weight, low hormone levels or low blood pressure (symptoms of which may include dizziness, headaches or fainting). In extreme cases this can be fatal. Your doctor will tell you how to stop using Betnesol Injection.

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

4. Possible side effects

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

Serious effects: tell a doctor straight away

Steroids including betamethasone can cause serious mental health problems. These are common in both adults and children. They may affect up to 1 in 10 people taking medicines like betamethasone.

If you notice any of the following problems, **talk to a doctor straight away:**

- **Feeling depressed, including thinking about suicide.**
- **Allergic reactions (which can include rashes, breathing difficulties or shock), blood disorders or heart failure.**
- **Changes in skin colour or blistering of the skin, mouth, eyes and genitals.**
- **Symptoms of cramping pain, redness, warmth or swelling in your arms or legs or shortness of breath. These could be a sign of a blood clot.**
- **Feeling high (mania) or moods that go up and down.**
- **Feeling anxious, having problems sleeping, difficulty in thinking or being confused and losing your memory.**
- **Worsening of epilepsy or schizophrenia, if you already have either of these problems.**
- **Feeling, seeing or hearing things which do not exist. Having strange and frightening thoughts, changing how you act or having feelings of being alone.**

- **Children may experience swelling and fluid build-up near the eyes and brain (this may result in a throbbing headache which may be worse upon waking up, coughing or sudden movement and patchy vision with blind spots and possible lack of colour vision).**
- **Increased eye pressure (glaucoma).**
- **Mouth and/or stomach ulcers, oesophageal ulcers (which may bleed)**
- **Symptoms of severe pain in your stomach, nausea and vomiting, diarrhoea, fever, loss of appetite and yellowing of your skin (jaundice). These could be a sign of acute pancreatitis.**

Most people find that using this medicine for a short time causes no problems. If you need to take the injections for more than 2 weeks, your doctor will prescribe as low as possible, dose.

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

High doses taken for a long period of time or repeated short courses, can lead to side-effects such as:

- Low levels of hormones, which can cause irregular menstrual periods in women, suppression of growth in adolescents and children, changes in blood sugar, salt or protein levels, extra hair growth and/or weight gain, increased sweating or increase in appetite.
- Increased levels of cholesterol in your blood.
- Increased susceptibility to infection, including worsening of tuberculosis (TB), if this is already present.
- Wasting of muscles, thinning of the bones (osteoporosis) or fractures, breaking of tendons and breakdown of the bone due to lack of blood supply.
- Water retention (which may cause a bloated feeling), higher blood pressure (symptoms may include headaches) or changes in blood chemistry due to loss of potassium.
- If you have recently had a heart attack, betamethasone can sometimes cause a serious complication of the heart, whereby the tissues can become affected by tears or breaks.
- Cataract, worsening of viral or fungal diseases, thinning of the cornea or sclera (the outer membrane of the eye) or other eye problems (which may cause headaches or blurred vision).
- Heartburn or indigestion, hiccups, nausea, bloating of the abdomen, thrush in the mouth or throat.
- Bruising, poor wound healing, abscesses, acne, rashes, thinning of the skin, prominent veins.

Additional care should be taken if this medicine is given to elderly, as side-effects may be more serious.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Betnesol Injection

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

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

Do not store above 25°C. Store in the original package in order to protect from light.

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 Betnesol Injection contains

-The active substance is betamethasone sodium phosphate. Each ampoule contains 5.3mg of betamethasone sodium phosphate equivalent to 4mg betamethasone in 1ml of sterile aqueous solution.

-The other ingredients are disodium edetate, sodium metabisulphite, sodium chloride, sodium hydroxide, hydrochloric acid and water for injection.

What Betnesol Injection looks like and contents of the pack

Betnesol Injection is a clear, colourless or pale yellow solution, supplied in ampoules containing 1ml, in boxes of 5.

Marketing Authorisation Holder

Focus Pharmaceuticals Ltd, Capital House, 85 King William Street, London EC4N 7BL, UK.

Manufacturer

Wasserburger Arzneimittelwerk GmbH, Herderstraße 2, D-83512 Wasserburg, Germany.

Carrying your steroid card

If your doctor asks you to carry a steroid card, be sure to keep it with you always.

Show it to any doctor, dentist, nurse, midwife or anyone else who is giving you treatment.

Even after your treatment has finished tell any doctor, dentist, nurse, midwife or anyone else who is giving you treatment that you have had steroid treatment.

A steroid card may be obtained from your doctor, nurse or local Family Health Service Authority. In Scotland, steroid cards are available from the Scottish Office of Home and Health.

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