Betamethasone 500 microgram Soluble Tablets

(betamethasone sodium phosphate)

Patient Information Leaflet

* **Betamethasone Soluble Tablets are a steroid medicine**, prescribed for many different conditions, including serious illnesses.
* **You need to take it regularly** to get the maximum benefit.
* **Do not stop taking this medicine** without talking to your doctor – you may need to reduce the dose gradually.
* **Betamethasone Soluble Tablets 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 taking 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 take it for more than three 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 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, pharmacist or nurse.
* 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet, Betamethasone 500 microgram Soluble Tablets will be called Betamethasone Soluble Tablets.

What is in this leaflet:

1. What Betamethasone Soluble Tablets are and what they are used for
2. What you need to know before you take Betamethasone Soluble Tablets
3. How to take Betamethasone Soluble Tablets
4. Possible side effects
5. How to store Betamethasone Soluble Tablets
6. Contents of the pack and other information

1 What Betamethasone Soluble Tablets are and what they are used for

Betamethasone Soluble Tablets belong 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 Betamethasone Soluble Tablets) is an effective way to treat various illnesses involving inflammation in the body. Betamethasone Soluble Tablets reduce this inflammation, which could otherwise go on making your condition worse. You must take 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.

Betamethasone Soluble Tablets are used to treat:
* asthma;
* severe allergic reactions;
* rheumatoid arthritis;
* autoimmune diseases such as systemic lupus erythematosus (SLE) and polyarteritis nodosa;
* inflammatory conditions of the skin, kidney (such as acute interstitial nephritis or minimal change nephrotic syndrome), bowels (such as ulcerative colitis and Crohn's disease) and heart;
* some connective tissue diseases;
* certain conditions of the blood;
* some types of cancer, such as malignant lymphoma.

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

2 What you need to know before you take Betamethasone Soluble Tablets

Do not take Betamethasone Soluble Tablets:
* 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 medicine (e.g. antibiotics) to treat it.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Betamethasone Soluble Tablets
* **if you have ever had severe depression or manic depression** (bipolar disorder). This includes having had depression before while taking steroid medicines like Betamethasone Soluble Tablets;
* **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;
* 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 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).
* if you experience blurred vision or other visual disturbances;
* if you have pheochromocytoma (a tumour of the adrenal gland).

Other medicines and Betamethasone Soluble Tablets
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 Betamethasone Soluble Tablets 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 contraceptive** (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.

Betamethasone Soluble Tablets may also affect the results of gallbladder X-ray procedures.

Mental problems while taking Betamethasone Soluble Tablets
Mental health problems can happen while taking steroids like Betamethasone Soluble Tablets (see also 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 happen they might need treatment.

Talk to a doctor if you (or someone who is taking this medicine), show 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 it 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 taking your tablets, 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 or pharmacist for advice before taking this medicine.

Pregnancy
Taking steroids often or for a long 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 taking this medicine, please tell your doctor but **DO NOT stop taking the tablets 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 taking high doses for a long time.

Betamethasone Soluble Tablets contains sodium and sodium benzoate. This medicine contains less than 1 mmol sodium (23 mg) per tablet, thatis to say essentially 'sodium-free'. For a dose ranging between two to ten tablets (1000 to 5000 micrograms per dose), this medicine contains between 41.8 mg and 209 mg sodium (main component of cooking/table salt) in each dose.
This is equivalent to 1.74% to 8.70% of the UK recommended maximum daily dietary intake of 2.4g sodium for an adult.

This medicine contains 6mg of sodium benzoate in each tablet. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

3 How to take Betamethasone Soluble Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Important:
Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it does not or you are not sure, ask your doctor or pharmacist.

You may have been given a **steroid card** which also tells you how many tablets to take each day (see section 6).

Betamethasone 500 microgram Soluble Tablets

(betamethasone sodium phosphate)

Patient Information Leaflet (continued)

Method of administration:
Your tablets can be swallowed whole, but they are best taken as a drink after allowing them to dissolve in a glass of water.

Do not exceed the stated dose.

Do not suddenly stop taking the tablets even if you feel better unless your doctor tells you to - you could become ill.

The dose used will depend upon the disease, its severity and how quickly you get better. The following doses are a guide only:
The recommended dose is
Adults
Short term treatment:
* 2000 - 3000 micrograms (4-6 tablets) daily for the first few days, then;
* Your doctor may reduce the daily dose by 250 - 500 micrograms (1/2 or 1 tablet) every two to five days, depending upon the response.

Rheumatoid arthritis:
* 500 - 2000 micrograms (1-4 tablets) daily;
* For long-term treatment the dose may be lower.

Most other conditions:
* 1500 - 5000 micrograms (3-10 tablets) daily for one to three weeks;
* Your doctor may then gradually reduce this to a lower dose;
* Larger doses may be needed for mixed connective tissue diseases and ulcerative colitis.

If you need to take half a tablet you should break one in half. Use the break line on one side of the tablet to help you snap it.

Use in children and adolescents
* A proportion of the adult dose may be used. Your doctor will advise how much.

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

While you are taking 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.

If you take more Betamethasone Soluble Tablets than you should
Do not take more Betamethasone Soluble Tablets than you should. If you accidentally take too much, immediately contact the nearest hospital casualty department or your doctor.

If you forget to take Betamethasone Soluble Tablets
Do not take a double dose to make up for a forgotten dose. Take your next dose at the usual time.

If you stop taking Betamethasone Soluble Tablets
Do not stop taking Betamethasone Soluble Tablets without first talking to your doctor.

It is very important that you do not suddenly stop taking Betamethasone Soluble Tablets, 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 taking your medicine too suddenly, you may suffer from some of the following: Fever, joint and muscle pain, itching eyes, nose or skin, mood changes, loss of weight, low hormone levels and 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 taking Betamethasone Soluble Tablets.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist 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 can affect about 5 in every 100 people taking medicines like betamethasone.
* **Feeling depressed, including thinking about suicide;**
* **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;**
* **Feeling, seeing or hearing things which do not exist. Having strange and frightening thoughts, changing how you act or having feelings of being alone.**

If you notice any of these problems talk to a doctor straight away.

Most people find that using this medicine for a short time causes no problems. If you need to take the tablets for more than two 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 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 increases 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) or 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;
* mood changes, depression, sleep problems or worsening of epilepsy or schizophrenia if you already have either of these problems;
* 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 pressure in the eye (glaucoma), 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, stomach ulcers which may bleed, oesophageal ulcer, thrush in the mouth or throat or pancreas disorders;
* bruising, poor wound healing, abscesses, acne, rashes, thinning of the skin, prominent veins, changes in skin colour or blistering of the skin, mouth, eyes and genital
* blood clots or allergic reactions (which can include rashes, breathing difficulties or shock), blood disorders or heart failure;
* blurred vision.

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

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed on this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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 Betamethasone Soluble Tablets

* **Keep out of the sight and reach of children.**
* Do not store above 25°C.
* Store in the original package in order to protect from light and moisture.
* Do not take Betamethasone Soluble Tablets after the expiry date shown on the blister or carton. The expiry date refers to the last day of that month.
* If your doctor tells you to stop using this medicine, take any remaining tablets back to the pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.
* If your tablets become discoloured or show any other signs of deterioration consult your pharmacist who will tell you what to do.
* Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Contents of the pack and other information

What Betamethasone Soluble Tablets contains:
Each tablet contains 500 micrograms betamethasone (as betamethasone sodium phosphate).
Also includes sodium benzoate, erythrosine (E127), povidone, saccharin sodium, sodium citrate and sodium bicarbonate.

What Betamethasone Soluble Tablets looks like and contents of the pack:
Small, round, soluble white 6.5mm tablets with a bevelled edge and a score line on one side.
Each pack contains 30 or 100 tablets.

Manufacturer and Licence Holder
Manufactured by Alfasigma S.p.A., Via Pontina, km 30,400, 00071 Pomezia (Rome), Italy and is procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

If you have any questions or are not sure about anything, ask your doctor or pharmacist. They will have additional information about this medicine and will be able to advise you.

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 or 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, pharmacist or local Family Health Service Authority. In Scotland, steroid cards are available from the Scottish Office of Home and Health.

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