

**BETNESOL® 500 microgram Soluble Tablets**  
**Betamethasone**  
**PATIENT INFORMATION LEAFLET**

- **Betnesol Tablets is a steroid medicine**, prescribed for many different conditions, including serious illnesses.
- **You need to take it regularly** to get the maximum benefit.
- **Don't stop taking this medicine** without talking to your doctor – you may need to reduce the dose gradually.
- **Betnesol Tablets can cause side effects in some people** (read section on side effects below). 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 (read section on side effects for more information).
- **If you take 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 chicken pox or shingles**, if you have never had them. They could affect you severely. If you do come into contact with chicken pox or shingles, **see your doctor straight away**.

**Now read the rest of this leaflet.** It includes other important information on the safe and effective use of this medicine that might be especially important for you. **This leaflet was last updated June 2009.**

If you have any questions about this medicine, ask your doctor or pharmacist.

#### **What is your medicine?**

Betnesol 500 micrograms Soluble Tablets are round, pink soluble tablets, scored one side and with 'Betnesol Evans' engraved on the other.

Each tablet contains 500 micrograms (0.5mg) betamethasone as betamethasone sodium phosphate. The tablets also contain sodium hydrogen carbonate (E500), sodium acid citrate, saccharin sodium, povidone, Erythrosine (E127) and sodium benzoate (E211). Betnesol Tablets are supplied in strip packs of 100 tablets.

The marketing authorisation holder is RPH Pharmaceuticals AB, Box 603, 101 32 Stockholm, Sweden and the manufacturer is Recipharm Ltd, Vale of Bardsley, Ashton-under-Lyne, OL7 9RR, UK.

Betnesol 500 mg Soluble Tablets 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 Tablets) is an effective way to treat various illnesses involving inflammation in the body. Betnesol Tablets reduces this inflammation, which could otherwise go on making your condition worse. You must take this medicine regularly to get the maximum benefit.

#### **What is your medicine used for?**

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

- Asthma and severe allergic reactions.
- Certain conditions of the blood.
- Rheumatoid arthritis.
- Autoimmune diseases such as systemic lupus erythematosus (SLE) and polyarteritis nodosa.
- Inflammatory conditions of the skin, kidney (such as acute interstitial nephritis), bowels (such as ulcerative colitis and Crohn's disease) and heart.
- Some connective tissue disorders.

- Some types of cancer, such as malignant lymphoma.

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

If you are not sure why you are on these tablets, ask your doctor.

### **Before using this medicine**

#### **Check with your doctor first**

- **If you have ever had severe depression** or manic depression (bipolar disorder). This includes having had depression before while taking steroid medicines like Betnesol Tablets.

- **If any of your close family** had had these illnesses.

If either of these applies to you, **talk to a doctor before taking Betnesol Tablets**.

- Have you taken Betnesol Tablets before and suffered a reaction to them, or been told that you are allergic to this medicine?

- Are you allergic to any of the ingredients in the tablets?

- Are you on a controlled sodium diet? If so, you should take into consideration that this medicinal product contains 20.9 mg sodium per tablet.

- Have you ever had tuberculosis (TB), epilepsy (fits), severe mental illness, glaucoma (raised eye pressure), hypertension (high blood pressure), osteoporosis (thinning of the bones), stomach or duodenal ulcers?

- Have you recently had a heart attack?

- Have you 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.

- Do you have an infection?

- Are you diabetic?

- Do you have an underactive thyroid gland?

- Have you ever suffered from muscle wasting due to corticosteroids?

- Do you have liver, kidney or heart disease?

- Have you just been or are you about to be immunised?

- Are you pregnant, likely to become pregnant, or breast-feeding? (see Special Precautions below)

- If you have pheochromocytoma (a tumour of the adrenal gland).

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

In particular: insulin or oral antidiabetic drugs; medicines for high blood pressure; water tablets (diuretics); medicines for thinning the blood eg. Warfarin; non-steroidal anti-inflammatory drugs eg. Aspirin; medicines for myasthenia gravis called anticholinesterases, medicines for the heart called cardiac glycosides; carbenoxolone; acetazolamide; rifampicin; rifabutin; carbamazepine, phenobarbitone; primidone; aminoglycethimide; ephedrine; theophylline; amphotericin B (anti-fungal); ritonavir; oral contraceptive (the pill); mifepristone; somatropin (growth hormone) vecuronium (relaxes muscles); fluoroquinolones (for some infections); quetiapine (improves symptoms of some mental illnesses); tretinoin (for skin problems such as bad acne).

Some medicines may increase the effects of Betnesol Tablets and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat)

### **What special precautions should be taken?**

#### **Mental problems while taking Betnesol Tablets**

Mental health problems can happen while taking steroids like Betnesol Tablets (see also section on possible side effects).

- 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), 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.

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 **Withdrawal Symptoms** below). If you are breastfeeding, the steroid may enter the baby and lower their hormone levels if you are taking high doses for a long time.

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.

Advise 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.

### **Visual problems while taking Betnesol Tablets**

Contact your doctor if you experience blurred vision or other visual disturbances.

### **How to use your medicine**

Look at the label; it should say *who* should use the tablets, *how many* should be taken and *when*. If it does not, or you are not sure, ask your doctor or pharmacist.

You may have been given a **STEROID CARD** which tells you how many tablets to take each day (see 'Carrying a steroid card').

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

If you need to take half a tablet, then use the line on one side of the tablet as a guide.

The tablets should be taken **EXACTLY** as stated on the label.

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

### **DO NOT EXCEED THE STATED DOSE**

#### **What are the usual doses?**

The dose used will depend upon the disease, its severity, and how quickly you get better. The following are for guidance only.

#### *Adults:*

Short term treatment: 2000-3000 micrograms (4-6 tablets) daily for the first few days, then reducing 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 lowest effective dosage is used.

Most other conditions: 1500-5000 micrograms (3-10 tablets) daily for one to three weeks, then gradually reducing to the minimum effective dosage. Larger doses may be needed for mixed connective tissue diseases and ulcerative colitis.

#### *Children:*

A proportion of the adult dosage may be used (e.g. 75% at 12 years, 50% at 7 years and 25% at 1 year).

### **What to do if you take too much**

If you take too many tablets, tell your doctor immediately.

### **What to do if you miss a dose**

If you forget to take a dose, take another as soon as possible, then go on as before. (If you only remember when it is time for your next dose, take a single dose and carry on as before).

### **Withdrawal Symptoms**

It is very important that you do not suddenly stop taking your medicine (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, low blood pressure (symptoms of which may include dizziness, headaches or fainting). In extreme cases this may be fatal.

### **Are there any side-effects to this medicine?**

**Serious effects: tell a doctor straight away.**

Steroids including dexamethasone 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 dexamethasone.

- 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**.

If you need to take the tablets for more than 2 weeks your doctor will prescribe as low a dose as possible. 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.
- 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).
- 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, blistering of the skin, mouth, eyes and genitals, acne, rashes, thinning of the skin, prominent veins, or changes in skin colour.
- Blood clots, or allergic reactions (which can include rashes, breathing difficulties or shock), blood disorders, or heart failure.

If you think this medicine has upset you in **ANY** way, **PLEASE TELL YOUR DOCTOR**. Additional care should be taken if this medicine is given to children or elderly patients, as side-effects may be more serious.

### **Storage of your medicine**

Do not store above 25°C. Store in the original package to protect from light. Do not use this medicine after the expiry date which is stated on the carton label and blister foil after EXP. The expiry date refers to the last day of that month.

**KEEP THIS AND ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN**

### **What to do with any unused tablets**

If your doctor decides to stop your medicine or you have tablets left at the end of treatment, return any unused tablets to your pharmacist for safe disposal.

### **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.**

**REMEMBER THIS MEDICINE IS ONLY FOR YOU. ONLY A DOCTOR CAN PRESCRIBE IT FOR YOU. NEVER GIVE IT TO SOMEONE ELSE; THERE MAY BE A REASON WHY IT COULD HARM THEM.**

### **Further Information**

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor (or pharmacist), who will have access to further information. Pharmaceutical companies are not allowed to advise about personal medical problems.

**YOU MAY WANT TO READ THIS LEAFLET AGAIN. PLEASE DO NOT THROW IT AWAY UNTIL YOU HAVE FINISHED YOUR MEDICINE.**

This leaflet only applies to Betnesol Tablets. Betnesol is a registered trade mark.

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