

## Package leaflet: Information for the patient

### Prednisolone 1mg/ml oral solution

Prednisolone sodium phosphate

**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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet.
  
- **Prednisolone is 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.
- Prednisolone Dompé can cause side effects in some people (read section 4 below). **Some side effects** 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 oral solution, 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 4 for more information).
- **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 may be especially important for you.

#### What is in this leaflet

1. What Prednisolone Dompé Oral Solution is and what it is used for
2. What you need to know before you take Prednisolone Dompé Oral Solution
3. How to take Prednisolone Dompé Oral Solution
4. Possible side effects
5. How to store Prednisolone Dompé Oral Solution
6. Content of the pack and other information

#### 1. What Prednisolone Dompé Oral Solution is and what it is used for

The full name of your medicine is ‘Prednisolone Dompé 1.0 mg/ml Oral Solution’, but in this leaflet it will be called ‘Prednisolone Dompé Oral Solution’. This medicine contains the active ingredient prednisolone, which belongs to a group of medicines called corticosteroids or “steroids”. Steroids work by reducing inflammation and lowering the body’s immune response.

Prednisolone Dompé Oral Solution is used to treat a variety of inflammatory diseases including severe asthma, rheumatoid arthritis, allergic reactions, severe skin conditions, and some blood disorders.

#### Prednisolone Dompé – benefit information

Prednisolone Dompé 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 prednisolone) is an effective way to treat various illnesses involving

inflammation in the body. Prednisolone Dompé reduces this inflammation, which could otherwise go on making your condition worse. You must take this medicine regularly to get maximum benefit from it.

## 2. What you need to know before you take Prednisolone Dompé Oral Solution

### Do not take Prednisolone Dompé Oral Solution:

- if you are **allergic** to prednisolone or any of the other ingredients of this medicine (listed in section 6). Allergic reactions include mild symptoms such as itching and/or rash. More severe symptoms include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing;
- if you have recently had a **vaccination** or have a vaccination planned.
- if you have a viral **infection** such as **measles, chickenpox or shingles** or any other infection. Tell your doctor **immediately** if you have come into contact with anyone suffering with measles, chickenpox or shingles in the last three months.
- If you have a tropical worm infections
- If you have systemic fungal infections

### Warnings and precautions

Talk to your doctor or pharmacist before taking Prednisolone Dompé Oral solution, especially if you have, have ever had or if anyone in your family has suffered from:

- **severe depression** or manic-depressive illness (bipolar disorder). This includes having had depression before or while taking steroid medicines like Prednisolone Dompé Oral Solution.
- TB (tuberculosis);
- diabetes;
- epilepsy;
- depression or other mental illness;
- an eye disease caused by a rise of pressure within the eye (glaucoma);
- thinning of the bones (osteoporosis);
- muscle problems when steroids were taken before;
- stomach ulcers;
- renal failure, high blood pressure, heart failure or recently suffered a heart attack;
- scleroderma (also known as systemic sclerosis, an autoimmune disorder) because daily doses of 15 mg or more may increase the risk of a serious complication called scleroderma renal crisis. Signs of scleroderma renal crisis include increased blood pressure and decreased urine production. The doctor may advise that you have your blood pressure and urine regularly checked;
- any liver problem;
- an under-active thyroid (hypothyroidism).

**If any of the above applies to you, or if you are not sure, talk to your doctor or pharmacist before you use this medicine.**

### Mental health problems while taking prednisolone

Mental health problems can occur while taking steroids like prednisolone (see also section 4, 'Possible side effects').

- These illnesses can be severe.
- 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 might need treatment.

**Talk to a doctor** if you (or someone taking this medicine) show any signs of mental health problems. This is particularly important if you are depressed or might be thinking about suicide. In a few cases, mental health problems have also happened when the doses have been lowered or the medicine stopped altogether.

**Talk to a doctor** if blurred vision, difficulty in reading or any other change in vision occurs during or after treatment.

Regular checkups with doctors (including vision checkups in three month-intervals) are advised during long term treatment.

**"If you take this medicine 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."

### **Carrying a Steroid card**

Your doctor or pharmacist will have given you a **Steroid Treatment Card** with your prescription or medicine. YOU SHOULD ALWAYS CARRY THIS CARD WITH YOU as it must be shown to any of the following persons:

**Doctor or Nurse** - before having any surgery or emergency treatment or if any new treatment is prescribed.

**Dentist** - before having any dental surgery.

**Pharmacist** - before buying any medicine.

**Optician** - it is advisable to have regular eye tests

### **Other medicines and Prednisolone Dompé Oral Solution**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

This is especially important if you are taking:

- Medicines for **epilepsy** such as carbamazepine, phenobarbitone, phenytoin or primidone;
- **Antibiotics** such as rifampicin, erythromycin;
- **Mifepristone** (used to terminate pregnancy);
- **Ritonavir** (used in HIV treatment);
- **Oral contraceptives**;
- **Somatropin** (used to treat growth problems);
- Medicines for **diabetes** such as insulin, glibenclamide or metformin;
- Medicines used to treat **high blood pressure**, such as diuretics (water tablets) like bendroflumethiazide and furosemide;
- **Warfarin** or other medicines used to thin the blood;
- **Aspirin** or similar medicines;
- **Theophylline** (used to treat asthma);
- Medicines to treat **fungal infections** such as amphotericin, ketoconazole;
- **Acetazolamide** (used to treat glaucoma);
- **Carbenoxolone** (used to treat stomach ulcers);
- **Methotrexate** (used for rheumatoid arthritis, psoriasis and certain types of cancer);
- Any medicine which belongs to a group of medicines called **sympathomimetics**;
- Medicines used to treat **myasthenia gravis**;
- Medicines used to make **x-rays clearer**;
- **Ciclosporin** (used to stop the body rejecting bone marrow or organ transplants).

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 Prednisolone Dompé oral solution and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

### **Pregnancy and breastfeeding and fertility**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

### Pregnancy

During pregnancy treatment should only be initiated after a careful benefit/risk assessment has been performed. Because growth retardation and damage to the unborn child cannot be excluded upon prolonged treatment with glucocorticoids during pregnancy, please inform your doctor if you want to become pregnant, are already pregnant or if you are assuming that you are pregnant.

#### Breastfeeding

Glucocorticoids, such as Prednisolone Dompé 1,0 mg/ml oral solution pass into breast milk. Damage to the infant is not reported to date. Nevertheless, when high doses of prednisolone are given you should avoid breast-feeding for 4 h after a dose. Please consult your doctor.

#### Fertility

After high prednisolone doses (30 mg/day for at least 4 weeks) reversible disturbances of spermatogenesis has been observed, which lasted for several months after stop taking the medicine.

#### **Driving and using machines**

This medicine should not affect your ability to drive or use machines.

#### **Prednisolone Dompé Oral Solution contains sucrose and glycerol**

This medicine contains 1,5 g of sucrose per dose. This should be taken into account in patients with diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains glycerol.

### **3. How to take Prednisolone Dompé Oral Solution**

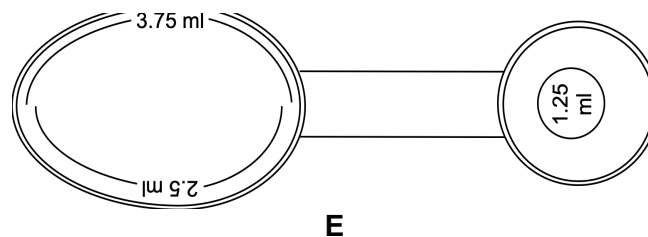
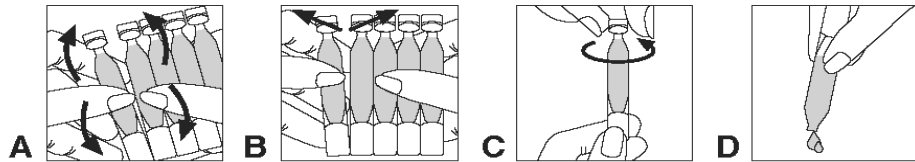
Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- It is best to take the oral solution undiluted.
- The solution should be taken by mouth.
- The solution should preferably be taken as a single dose in the morning. However, divided daily dosage may be employed if required.
- In children, the medicine should preferably be taken as a single dose on alternate days.
- Shake well before use.
- If you are on long-term therapy, make sure your supply of oral solution does not run out.
- Since opening many containers in the same day could lead to dosing errors, this 5 ml presentation is suitable for treatments not exceeding 30 mg daily. The dosage depends on the condition being treated and, for an adult, can vary widely between 10 mg and 30 mg daily in divided doses. Your doctor will give you the smallest dose that works for your condition.
- When you need to take more than two units all at once, each opened unit should be placed on a tray or suitable surface after opening and dispensing the content. This can help you avoiding dosing errors due to loss of count.
- The package contains a measuring spoon dosing 3.75 ml, 2.5 ml and 1.25 ml corresponding to partial doses.
- All opened units should be discarded once the required dose is removed.

#### **Instruction for use**

1. Flex the single-dose container in the two directions (see figure A).
2. Separate the single-dose container from the strip (see figure B).
3. Turn the cap counter clockwise as indicated in figure C.
4. Apply mild pressure on the container to dispense the medicine as prescribed (see figure D). For the dose of 5 ml, drink the full amount of the single-dose container. In case a partial dose has to be dispensed, the measuring spoon included in the package should be used to dispense 1.25 ml, or 2.5 ml, or 3.75 ml (see figure E).

5. After administering a partial dose, the opened container must be discarded.



#### Use in children

To treat acute asthma attacks, your child's doctor may prescribe:

- For children **younger than 2 years old**, 10 mg daily, for up to three days;
- For children **2 to 5 years old**, 20 mg daily. Treatment for up to three days is usually sufficient, but the length of the course will be decided by your doctor, according to the number of days necessary to recover.
- For children **older than 5 years old**, 30 mg daily or more (up to 40 mg daily). Since opening many containers in the same day could lead to dosing errors, in case more than 30 mg daily have been prescribed, ask your child's doctor, as a different prednisolone presentation (e.g. high dosage tablets) might be more appropriate.

If you have the impression that the effect of this medicine is too strong or too weak, talk to your doctor or pharmacist.

#### If you take more Prednisolone Dompé Oral Solution than you should

If you take more Prednisolone Dompé Oral Solution than prescribed, contact your doctor or nearest hospital emergency department **immediately**. Take this leaflet and/or the package with you to show the doctor what you have taken.

#### If you forget to take Prednisolone Dompé Oral Solution

If you forget to take Prednisolone Dompé Oral Solution, take the next dose as soon as you remember unless it is almost time for your next dose. **Do not** take a double dose to make up for a forgotten dose.

#### If you stop taking Prednisolone Dompé Oral Solution

**Talk to your doctor** if you want to stop taking the oral solution – your doctor may want to reduce your dose gradually.

**Do not stop** taking the oral solution unless you have been told to do so by your doctor, even if you feel better, as it can make you ill. If you stop taking the oral solution suddenly, this can cause withdrawal symptoms such as fever, sickness, pain in the muscles and joints, runny nose, sore, red and sticky eyes (conjunctivitis), itchy skin and weight loss.

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

#### 4. Possible side effects

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

Steroids including prednisolone can cause **severe mental health problems**, such as those listed below. These are common in both adults and children. **If you notice any of these problems talk to a doctor immediately:**

- Feeling depressed, including thinking about suicide.
- Feeling high (mania) or having moods that go up and down.
- Feeling anxious, having problems sleeping, having difficulty in thinking or being confused and losing your memory.
- Feeling, seeing or hearing things which do not exist (hallucinations). Having strange and frightening thoughts, changing how you act or having feelings of being alone.

**The following side effects may be signs of an allergic reaction. If you notice any of the below, stop taking Prednisolone Dompé Oral Solution and tell your doctor immediately:**

- itching or skin rashes;
- swelling of the face, lips or throat;
- difficulty in breathing or wheeziness.

**The following side effects can occur if steroids are given in high doses for a long time:**

- generally feeling unwell;
- feeling sick (nausea);
- hiccups;
- indigestion or stomach discomfort;
- stomach ulcer (which can rupture and bleed) or ulcer in the oesophagus (gullet);
- thrush;
- inflammation of the pancreas causing abdominal pain (pancreatitis) ;
- muscle weakness;
- muscle pain;
- thinning of bones which makes fractures more likely (osteoporosis);
- damage to tendons;
- joint stiffness causing limited movement, pain and muscle spasms;
- fluid retention causing swelling;
- feeling dehydrated;
- high blood pressure (hypertension);
- slow healing of wounds, thinning of the skin, bruising, acne, marks which look like stretch marks;
- small red, purple or blue spots found along the surface of the skin (caused by blood vessels under the skin);
- low adrenal gland function;
- slowed growth in infants, children and teenagers;
- irregular or stopped menstrual periods;
- swollen round face (*Cushingoid facies* or moon-face);
- excess hair growth;
- increased appetite and weight gain;
- intolerance to carbohydrates;
- mood changes, dependence, depression, difficulty sleeping, worsening of schizophrenia;
- severe headaches with blurred vision or temporary visual problems in children (usually after stopping treatment);
- worsening of epilepsy;
- raised pressure in the eyes (glaucoma), cataracts, thinning and inflammation of the cornea (part of the eye), worsening of viral or fungal eye diseases, blurred vision and visual impairment, choroid and retinal disorders (chorioretinopathy);

- heart attack (sudden severe chest pains);
- changes in body chemistry;
- increase in the number of white blood cells;
- formation of blood clots;
- porphyria
- Steven-Johnson syndrome
- long-term use of high dose steroids, may lead to a weakening of the immune system, which can increase the risk of your condition getting worse (malignancy).
- Not known: slow heart rate

Scleroderma renal crisis in patients already suffering from scleroderma (an autoimmune disorder). Signs of scleroderma renal crisis include increased blood pressure and decreased urine production.

Kaposi's sarcoma (a type of cancer) has also been reported to occur in patients receiving corticosteroids. However, once the treatment has been stopped, this may go away.

This medicine can make it easier for you to pick up infections which may very rarely be fatal. Infections such as chickenpox and measles can be made worse or TB (tuberculosis) may recur.

### **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 in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

[www.mhra.gov.uk/yellowcard](http://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 Prednisolone Dompé Oral Solution**

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

Store your oral solution in a safe place below 30°C. Store in the original package.

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

Container for single use only. Once opened you must discarded any unused solution.

Do not throw away any medicine 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 Prednisolone Dompé Oral Solution contains**

- The active substance is prednisolone (as sodium phosphate). One (1) ml of oral solution contains 1 mg prednisolone (as sodium phosphate).
- The other ingredients are: sucrose, glycerol, edetate disodium (EDTA), disodium phosphate anhydrous, sodium dihydrogen phosphate monohydrate, vanilla/cream flavour, honey flavour, masking flavour, Water for injections.

### **What Prednisolone Dompé Oral Solution looks like and contents of the pack**

Prednisolone Dompé Oral Solution is a clear, light brown, homogeneous solution.

It is available in single-dose polyethylene containers. One container has 5 ml of oral solution. Containers are grouped in strips of five. Each strip is packaged in a PET/Al/PE over-pouch. Each unit carton contains two over-pouches (ten single-doses), a measuring spoon (dosing 3.75 ml, 2.5 ml and 1.25 ml, corresponding to partial doses) and a patient leaflet.

Pack size of 10 single-dose containers.

**Marketing Authorization Holder and Manufacturer**

**Marketing Authorisation Holder**

Dompé farmaceutici S.p.A.  
Via San Martino 12  
20122 Milano - Italy

**Manufacturer**

GENETIC SpA – Contrada Canfora – Nucleo Industriale 84084 Fisciano- Salerno (Italy)

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