

## Package leaflet: Information for the patient

### **Medrone® Tablets 100 mg** methylprednisolone

**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. See section 4.

#### **What is in this leaflet**

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

#### **1. What Medrone is and what it is used for**

This medicine contains methylprednisolone, which belongs to a group of medicines called steroids. Their full name is corticosteroids. Corticosteroids are produced naturally in your body and are important for many body functions.

Boosting your body with extra corticosteroid such as Medrone can help following surgery (e.g. organ transplants), injuries or other stressful conditions. These include inflammatory or allergic conditions affecting the:

- **brain** (e.g., tuberculous meningitis)
- **bowel and gut** (e.g., Crohn's disease and ulcerative colitis)
- **blood or blood vessels** (e.g., leukaemia or arteritis, inflammation of the arteries)
- **joints** (e.g., rheumatic fever)
- **lungs** (e.g., asthma, tuberculosis)
- **muscle** (e.g., dermatomyositis and polymyositis)
- **skin** (e.g., pemphigus vulgaris, an auto-immune disorder in which the body's immune system is overactive causing the skin to blister)

Medrone may be prescribed to treat conditions other than those listed above.

You must talk to a doctor if you are unsure why you have been given this medicine, if you do not feel better or if you feel worse.

## 2. What you need to know before you take Medrone

### Do not take Medrone

- If you think you have ever suffered an **allergic reaction**, or any other type of reaction after being given Medrone or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may cause a skin rash or reddening, swollen face or lips or shortness of breath.
- If you have any **serious fungal infection** such as a serious fungal infection in your lungs or oesophagus (the tube that connects your mouth with your stomach) or any other infection which is not being treated with an antibiotic or antiviral medicine.
- If you have recently had or are about to have any **vaccination**.

If you get a rash or another symptom of an infection **tell your doctor immediately**.

### Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine if you have any of the following conditions. Your doctor may have to monitor your treatment more closely, alter your dose or give you another medicine.

- **Chickenpox, measles or shingles.** If you think you have been in contact with someone with chickenpox, measles or shingles and you have not already had these illnesses, or if you are unsure if you have had them.
- **Worm infestation** (e.g., threadworm).
- Severe **depression** or **manic depression** (bipolar disorder). This includes having had depression before while taking steroid medicines like Medrone, or having a family history of these illnesses.
- **Diabetes** (or if there is a family history of diabetes).
- **Fits or seizures.**
- **Glaucoma** (increased pressure in the eye) or if there is a family history of glaucoma, or if you have **cataracts**.
- Contact your doctor if you experience **blurred vision or other visual disturbances**.
- **Viral** (e.g., herpes) or **fungal** eye infection.
- You recently suffered a **heart attack**.
- **Heart problems**, including heart failure.
- **Hypertension** (high blood pressure).
- **Hypothyroidism** (an under-active thyroid).
- **Hyperthyroidism** (an over-active thyroid gland).
- **Pancreatitis** (inflammation of the pancreas which causes severe pain in the abdomen and back).
- **Peritonitis** (inflammation of the thin lining (peritoneum) around the gut and stomach).
- **Kidney or liver** disease.
- **Scleroderma** (also known as systemic sclerosis, an autoimmune disorder), because the risk of a serious complication called scleroderma renal crisis may be increased. Signs of scleroderma renal crisis include increased blood pressure and decreased urine production.
- **Kaposi's sarcoma** (a type of skin cancer).
- **Muscle problems** (pain or weakness) have happened while taking steroid medicines like Medrone in the past.
- **Myasthenia gravis** (muscle disease with muscle fatigue), or if during treatment you develop muscular disorders.
- **Osteoporosis** (brittle bones).

- **Pheochromocytoma** (a rare tumour of adrenal gland tissue. The adrenal glands are located above the kidneys).
- **Skin abscess.**
- **Stomach ulcer** or other serious stomach or intestinal problems.
- **Thrombophlebitis** - vein problems due to thrombosis (clots in the veins) resulting in phlebitis (red, swollen and tender veins).
- **Tuberculosis (TB)** or if you have suffered tuberculosis in the past.
- **Cushing's disease** (condition caused by an excess of cortisol hormone in your body).
- **Brain injury** due to trauma (injury).
- Unusual **stress.**

Contact your doctor promptly if you experience muscle weakness, muscle aches, cramps and stiffness while using methylprednisolone. These can be symptoms of a condition called Thyrotoxic Periodic Paralysis which may occur in patients with an over-active thyroid gland (hyperthyroidism) who are treated with methylprednisolone. You may need additional treatment to alleviate this condition.

Tumour lysis syndrome (TLS) can occur after treatment of a fast-growing cancer, such as blood cancers or solid tumours. Symptoms of TLS include muscle cramping, muscle weakness, confusion, irregular heartbeat, visual loss or visual disturbances, and shortness of breath. Your doctor will monitor you closely, especially if you are at high risk of developing tumour lysis syndrome.

Contact your doctor immediately, if you experience any muscle pain, muscle weakness, and /or red-brown change in the colour of your urine as this might be a sign of rhabdomyolysis which is a severe condition involving breakdown of your muscles.

### Other medicines and Medrone

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, (including medicines you have obtained without a prescription). This could be harmful or affect the way Medrone or the other medicine works:

- **Acetazolamide** - used to treat glaucoma and epilepsy.
- **Aminoglutethimide** or **Cyclophosphamide** – used for treating cancer.
- **Oral anticoagulants** of the vitamin K antagonists class - used to treat and prevent blood clots blocking the blood vessels such as acenocoumarol, fluindione, phenindione and warfarin.
- **Anticholinesterases** - used to treat myasthenia gravis (a muscle condition) such as distigmine and neostigmine.
- **Antibacterials** (such as isoniazid, erythromycin, clarithromycin and troleandomycin).
- **Antidiabetics** – medicines used to treat high blood sugar.
- **Aprepitant** or **fosaprepitant** – used to prevent nausea and vomiting.
- **Aspirin** and non-steroidal anti-inflammatory medicines (also called **NSAIDs**) such as ibuprofen used to treat mild to moderate pain.
- **Barbiturates, carbamazepine, phenytoin** and **primidone** – used to treat epilepsy.
- **Carbenoxolone** and **cimetidine** - used for heartburn and acid indigestion.
- **Ciclosporin** - used to treat conditions such as severe rheumatoid arthritis, severe psoriasis or following an organ or bone marrow transplant.
- **Digoxin** - used for heart failure and/or an irregular heartbeat.
- **Diltiazem** or **mibefradil** – used for heart problems or high blood pressure.
- **Ethinylestradiol** and **norethisterone** – an oral contraceptive.

- **Antivirals** (such as ritonavir, indinavir) and **pharmacokinetic enhancers** (such as cobicistat) used to treat HIV infections.
- **Ketoconazole** or **itraconazole** – used to treat fungal infections.
- **Pancuronium, vecuronium** – or other muscle relaxants called neuromuscular blocking agents which are used in some surgical procedures.
- **Potassium depleting agents** – such as **diuretics** (sometimes called water tablets), **amphotericin B, xanthenes or beta2 agonists** (e.g., medicines used to treat asthma).
- **Rifampicin** and **rifabutin** – antibiotics used to treat tuberculosis (TB).
- **Tacrolimus** – used following an organ transplant to prevent rejection of the organ.
- **Vaccines** - tell your doctor or nurse if you have recently had, or are about to have any vaccination. You **must not** have ‘live’ vaccines while using this medicine. Other vaccines may be less effective.

#### **If you are taking long term medication(s)**

If you are being treated for diabetes, high blood pressure or water retention (oedema) tell your doctor as he/she may need to adjust the dose of the medicines used to treat these conditions.

**Before you have any operation** tell your doctor, dentist or anesthetist that you are taking Medrone.

**If you require a test to be carried out by your doctor or in hospital** it is important that you tell the doctor or nurse that you are taking Medrone. This medicine can affect the results of some tests.

#### **Pregnancy and breast-feeding**

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine, as it could slow the baby’s growth. There is a risk of low birth weight of a baby; this risk can be minimised by taking the lowest effective dose of the corticosteroids.

Cataracts have been observed in infants born to mothers treated with long-term corticosteroids during pregnancy.

If you are breast-feeding, ask your doctor or pharmacist for advice, as small amounts of corticosteroid medicines may get into breast milk.

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

Undesirable effects, such as dizziness, vertigo, visual disturbances and fatigue are possible after treatment with corticosteroids. If you are affected do not drive or operate machinery.

#### **Medrone contains sodium**

This medicine contains less than 1 mmol (23 mg) sodium per tablet, that is to say essentially ‘sodium-free’.

### **3. How to take Medrone**

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

#### **Steroid Cards**

**Remember to always carry a Steroid Treatment Card. Make sure your doctor or pharmacist has filled out the details of your medicine, including the dose and how long you will require steroid treatment.**

You should show your steroid card to **anyone** who gives you treatment (such as a doctor, nurse or dentist) while you are taking Medrone, and for 3 months after you stop taking the tablets.

If you are admitted to hospital for any reason always tell your doctor or nurse that you are taking Medrone. You can also wear a medic-alert bracelet or pendant to let medical staff know that you are taking a steroid if you have an accident or become unconscious.

### **Adults**

The normal daily dose is between 4 mg and 360 mg per day, depending on your condition and how severe it is. Your doctor will prescribe the lowest dose possible.

Your doctor may tell you to take your daily dose all in one go, split your daily dose throughout the day, or take it every other day at 8.00 am.

Swallow the tablets **whole** with a drink of water. The score line is not intended for breaking the tablet. Do not eat grapefruit or drink grapefruit juice while taking Medrone.

If you are being given Medrone because your body cannot make its own corticosteroids, your doctor may also want you to take a second type of steroid to help your salt balance.

Your doctor may prescribe a higher dose at the start of your treatment to bring your condition under control.

When your doctor is happy that your condition has improved your dose will be reduced gradually. Normally the dose will be reduced by not more than 2 mg every 7 to 10 days.

### **Elderly:**

Your doctor may want to see you more regularly to check how you are getting on with your tablets.

### **Children and adolescents:**

Corticosteroids can affect growth in children so your doctor will prescribe the lowest dose that will be effective for your child. Your doctor may tell you to give your child this medicine on every other day.

### **If you take more Medrone than you should**

It is important that you do not take more tablets than you are told to take. If you accidentally take too many tablets, seek medical attention straight away.

### **If you forget to take your Medrone**

Wait and take the next dose as normal. Do not take a dose to make up for the forgotten one but tell your doctor or pharmacist what had happened.

### **Stopping/reducing the dose of your Medrone**

Your doctor will decide when it is time to stop your dose.

**You must not stop taking Medrone suddenly**, especially if you:

- have had more than 6 mg Medrone daily for more than 3 weeks
- have been given high doses of Medrone (more than 32 mg daily) even if it was only for 3 weeks or less

- have already had a course of corticosteroid tablets or injections in the last year
- already had problems with your adrenal glands (adrenocortical insufficiency) before you started this treatment
- take repeat doses in the evening.

You will need to come off Medrone slowly to avoid **withdrawal symptoms**. These symptoms may include itchy skin, fever, muscle and joint pains, runny nose, sticky eyes, loss of appetite, nausea, vomiting, headache, feeling tired, peeling skin and weight loss.

If your symptoms seem to return or get worse as your dose of Medrone is reduced tell your doctor immediately.

### **Mental problems while taking Medrone**

Mental health problems can happen while taking steroids like Medrone (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 the problems do happen they might need treatment.

Talk to a doctor if you (or someone 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.

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. Your doctor will have given you this medicine for a condition which if not treated properly could become serious.

These side effects may occur with certain frequencies, which are defined as follows:

- *common*: may affect up to 1 in 10 people.
- *rare*: may affect up to 1 in 1,000 people.
- *not known*: frequency cannot be estimated from the available data.

**In certain medical conditions medicines like Medrone (steroids) should not be stopped abruptly. If you suffer from any of the following symptoms, seek IMMEDIATE medical attention. Your doctor will then decide whether you should continue taking your medicine:**

#### *common*

- **Burst or bleeding ulcers**, symptoms of which are stomach pain (especially if it seems to spread to your back), bleeding from the back passage, black or bloodstained stools and/or vomiting blood.
- **Infections**. This medicine can hide or change the signs and symptoms of some infections, or reduce your resistance to the infection, so that they are hard to diagnose at an early stage. Symptoms might include a raised temperature and feeling unwell. Symptoms of a flare up of a

previous TB infection could be coughing blood or pain in the chest. Medrone may also make you more likely to develop a severe infection.

*not known*

- **Allergic reactions**, such as skin rash, swelling of the face or wheezing and difficulty breathing. This type of side effect is rare, but can be serious.
- **Pancreatitis**, stomach pain spreading to your back, possibly accompanied by vomiting, shock and loss of consciousness.
- **Pulmonary embolus** (blood clots in the lung), symptoms of include sudden sharp chest pain, breathlessness and coughing up blood.
- **Raised pressure within the skull** of children (pseudotumour cerebri) symptoms of which are headaches with vomiting, lack of energy and drowsiness. This side-effect usually occurs after treatment is stopped.
- **Thrombophlebitis** (blood clots or thrombosis in a leg vein), symptoms of which include painful swollen, red and tender veins.

**If you experience any of the following side effects, or notice any other unusual effects not mentioned in this leaflet, tell your doctor straight away:**

### **Blood, heart and circulation**

*common*

- High blood pressure, symptoms of which are headaches, or generally feeling unwell.

*not known*

- Problems with the pumping of your heart (heart failure) symptoms of which are swollen ankles, difficulty in breathing and palpitations (awareness of heart beat) or irregular beating of the heart, irregular or very fast or slow pulse.
- Increased numbers of white blood cells (leukocytosis).
- Warmth and reddening of the skin (flushing).
- Low blood pressure.

### **Body water and salts**

*common*

- Swelling and high blood pressure, caused by increased levels of water and salt content.
- Cramps and spasms, due to the loss of potassium from your body. In rare cases this can lead to congestive heart failure (when the heart cannot pump properly).

*not known*

- Increased blood urea levels.

### **Digestive system**

*not known*

- Nausea (feeling sick) or vomiting (being sick).
- Ulcers, inflammation or thrush in the oesophagus (the tube that connects your mouth with your stomach), which can cause discomfort on swallowing.
- Inflammation of the thin lining (peritoneum) around the gut and stomach.
- Indigestion.
- Bloating stomach.
- Abdominal pain.
- Diarrhoea.
- Persistent hiccups, especially when high doses are taken.

## **Eyes**

*common*

- Damage to the optic nerve or cataracts (indicated by failing eyesight).

*rare*

- Blurred vision.

*not known*

- Glaucoma (raised pressure within the eye, causing pain in the eyes and headaches).
- Swollen optic nerve (papilloedema, indicated by sight disturbance).
- Thinning of the clear part at the front of the eye (cornea) or of the white part of the eye (sclera).
- Worsening of viral or fungal eye infections.
- Protruding of the eyeballs (exophthalmos).
- Blurred or distorted vision (due to a disease called chorioretinopathy).

## **Hepatobiliary disorders**

*not known*

- Increase of liver enzymes.

## **Hormone and metabolic system**

*common*

- Slowing of normal growth in infants, children and adolescents which may be permanent.
- Round or moon-shaped face (Cushingoid facies).

*not known*

- Irregular or no periods in women.
- Increased hair on the body and face in women (hirsutism).
- Increased appetite and weight gain.
- Abnormal blood level of lipids (e.g. cholesterol and/or fat).
- Diabetes or worsening of existing diabetes.
- Prolonged therapy can lead to lower levels of some hormones which in turn can cause low blood pressure and dizziness. This effect may persist for months.
- The amount of certain chemicals (enzymes) called alanine transaminase, aspartate transaminase and alkaline phosphatase that help the body digest drugs and other substances in your body may be raised after treatment with a corticosteroid. The change is usually small and the enzyme levels return to normal after your medicine has cleared naturally from your system. You will not notice any symptoms if this happens, but it will show up if you have a blood test.
- Accumulation of fat tissue on localised parts of the body, manifesting as different presentations for example back pain or weakness (due to epidural lipomatosis).

## **Immune system**

*not known*

- Increased susceptibility to infections which can hide or change normal reactions to skin tests, such as that for tuberculosis.

## **Muscles and bones**

*common*

- Muscle weakness or wasting.

*not known*

- Brittle bones (bones that break easily).
- Broken bones or fractures.
- Breakdown of bone due to poor circulation of blood, this causes pain in the hip.

- Joint pain or joint problems.
- Torn muscle tendons causing pain and/or swelling.
- Muscle cramps or spasms.
- Aching muscles, muscle tenderness or weakness, not caused by exercise (myopathy).
- Muscle weakness or pain which in some cases can be associated with abnormal breakdown of muscle tissue (rhabdomyolysis).
- Change in urine colour to red-brown (rhabdomyolysis).

### **Nervous system**

Steroids including methylprednisolone 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 methylprednisolone.

- 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.

*not known*

- Irritability.
- Fits.
- Dizziness, a feeling of dizziness or 'spinning'.
- Headache.

### **Skin**

*common*

- Acne.
- Poor wound healing.
- Thinning of skin.

*not known*

- Stretch marks.
- Bruising.
- Sweating.
- Itchy skin.
- Rash or redness of skin.
- Hives (red itchy swellings).
- Dilation of small blood vessels on the surface of the skin (red spider veins).
- Red, brown or purple, pin point, round spots.
- Brown/purple/red raised patches on the skin or inside the mouth (Kaposi's sarcoma).
- Inflammation of the fatty tissue under the skin which can make the skin feel hard and possibly develop painful red lumps or patches (panniculitis). Panniculitis may occur following dose reduction or discontinuation of methylprednisolone and has been more frequently reported in children.

### **Vascular disorders**

*not known*

- Increased clotting of the blood

## **Other side effects**

*not known*

- Feeling unwell.
- Feeling tired.
- Accumulation of fluid causing swelling in the body, especially the lower limbs.
- Suppression of reactions to skin tests.

It is important if you are to have a blood test that you tell the doctor or nurse that you have been given treatment with Medrone.

**If you experience any of the side effects listed above tell your doctor straight away.**

## **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) 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 Medrone**

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 bottle and carton after 'EXP'. The expiry date refers to the last day of that month.

Store below 25°C.

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 Medrone tablets contain**

The active substance is methylprednisolone. Each tablet contains 100 mg methylprednisolone.

The other ingredients are methylcellulose, sodium starch glycollate (see section 2 "Medrone contains sodium"), microcrystalline cellulose, magnesium stearate and indigo carmine (E132).

### **What Medrone tablets look like and contents of the pack**

Medrone Tablets 100 mg are light blue, round, scored with a cross and marked 'UPJOHN 3379'.

It is available in high density polyethylene (HDPE) bottles of 20, 25, 30 or 100 tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Pfizer Limited, Ramsgate Road, Sandwich, Kent CT13 9NJ.

### **Manufacturer**

Pfizer Italia S.r.l., Località Marino del Tronto, 63100 Ascoli Piceno (AP), Italy.

**Company Contact Address:**

For further information on your medicine contact Medical Information at Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS. Tel: 01304 616161.

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