

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about PredMix Oral Liquid. It does not contain all the information that is known about PredMix Oral Liquid.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking PredMix Oral Liquid against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

### What PredMix Oral Liquid is used for

PredMix Oral Liquid contains prednisolone sodium phosphate which is changed to prednisolone after it enters the body.

Prednisolone belongs to a group of medicines called corticosteroids. It is a synthetic version of a naturally occurring body hormone called cortisol.

It works by entering inflammatory cells and blocking the inflammatory reaction. This medicine is only able to prevent or reduce symptoms of your condition, it does not cure it.

PredMix Oral Liquid is used in the treatment of many different conditions. Some of these conditions include: severe allergies, severe or chronic asthma, skin problems, arthritis, inflammatory diseases of the bowel, cancer and "auto-immune" diseases.

PredMix Oral Liquid is also used to prevent or reduce the symptoms of inflammation (such as swelling, redness, pain, tenderness or itching) in any part of the body. These symptoms can occur in response to injury or can be caused by many different conditions.

**Ask your doctor if you have any questions about why PredMix Oral Liquid has been prescribed for you.**

Your doctor may have prescribed it for another reason.

This medicine is only available with a doctor's prescription.

There is no evidence that it is addictive.

### Before you take it

#### *When you must not take it*

**Do not take PredMix Oral Liquid if you have ever had an allergic reaction to:**

- prednisolone or prednisone
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue or any other parts of the body; rash, itching or hives on the skin.

**Do not take it if you have a current serious or uncontrolled infection, including fungal infections.**

**Do not take PredMix Oral Liquid after the expiry date printed on the label.**

It may have no effect at all or an entirely unexpected effect if you take it after the expiry date.

**Do not take it if the packaging shows signs of having been tampered with.**

**Do not take this medicine to treat any other complaints unless your doctor has instructed you to do so.**

**Do not give this medicine to anyone else.**

*Before you start to take it*

**Tell your doctor if you are allergic to any other medicines or any foods, dyes or preservatives.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- a current serious or uncontrolled infection, including fungal infections
- recent surgery or serious injury
- diabetes mellitus (sugar diabetes)
- osteoporosis (softening of the bone)
- a stomach ulcer or other stomach or intestinal problems
- liver, kidney or heart disease
- tuberculosis
- epilepsy
- muscle weakness
- glaucoma (high pressure in the eye) or cataracts
- thyroid disease
- high blood pressure.

**Do not take PredMix Oral Liquid if you are pregnant or plan to become pregnant.**

It is not generally recommended for use in pregnant women unless the benefits of treatment outweigh the risk to the unborn baby.

**Do not take it if you are breast feeding or plan to breast feed.**

It is not recommended for use while breast feeding as this medicine is found in breast milk.

**If you have not told your doctor about any of these things, tell them before you take PredMix Oral Liquid.**

#### *Taking other medicines*

**Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.**

Some medicines may interfere with PredMix Oral Liquid. These include:

- antacids (in large amounts)
- medicines for diabetes
- some medicines for heart disease
- medicines for removal of fluid (diuretics)
- some medicines for epilepsy
- some types of antibiotics
- potassium or salt supplements
- immunisations or vaccines
- high dose aspirin
- drugs which prevent blood clots.

These medicines may be affected by PredMix Oral Liquid or may affect how well it works. You may need to take different

amounts of your medicine or you may need to take different medicines. Your doctor or pharmacist has a more complete list of medicines to be careful with or avoid while taking this medicine.

#### *Use in children*

PredMix Oral Liquid should only be used in children under your doctor's supervision.

If possible, children should not be exposed to common childhood illnesses such as chickenpox or measles while they are taking this medicine. They may suffer from more serious attacks of these illnesses if such exposure occurs.

Children should not be vaccinated with "live" vaccines against common childhood illnesses while they are taking it, as this may result in severe attacks of these illnesses.

Potentially serious side effects can occur in children and growing teenagers who are taking corticosteroids. Some of these include obesity, slowed growth, osteoporosis (softening of the bone) and changes in the adrenal glands.

#### *Use in elderly*

Elderly patients may be more sensitive to the effects or side effects of this medicine.

### How to take it

#### *How much to take*

**Follow all directions given to you by your doctor and pharmacist carefully.**

These directions may differ from the information contained in this leaflet.

The dose will depend on the condition being treated and your response to the treatment.

Your initial dose will be maintained or adjusted until a satisfactory response is noted.

#### *How to take it*

**Do not add anything to the PredMix Oral Liquid bottle itself.**

Your dose of PredMix Oral Liquid can be mixed with milk, cordial, soft drink, soft food or you can take it by itself. You will soon know how you prefer to take the medicine.

#### *When to take it*

How often PredMix Oral Liquid can be taken may vary depending on what condition is being treated. It can be taken once daily, several times a day or on alternate days.

If you take it once a day or every second day, then it is best taken at breakfast time. If it needs to be taken more than once a day, then space it out during the day.

#### *How long to take it*

**Continue taking PredMix Oral Liquid for as long as your doctor tells you.**

This will depend on your condition and on your response to treatment. Some people will need this medicine for only short periods of time whilst others may require long term therapy.

**Do not miss any doses and do not stop taking the medicine even if you feel better.** Missing doses may make your symptoms worse.

## What to expect

Individuals will vary greatly in their response to PredMix Oral Liquid. Your doctor will check your progress at regular intervals.

### *If you forget to take it*

If you miss a dose of this medicine the decision of whether you should take it or not will depend on how many times a day you take PredMix Oral Liquid.

If you are taking PredMix Oral Liquid:

- once a day-  
If you miss a dose and remember in less than 12 hours, take it straight away, then continue as normal the next day.  
Otherwise, skip that day's dose but be sure to take the next day's dose when it is due.
- several times a day-  
If you miss a dose and it is more than 2 hours before your next dose is due, take it straight away, then continue as you normally would. If it is less than 2 hours to your next dose, skip the dose you have missed but be sure to take the next dose when you are meant to.
- on alternate days-  
If you miss a dose and remember it the same morning, take it straight away then continue as you normally would. If you do not remember the missed dose until later, wait and take it the following morning. Then skip a day before continuing your regular dosage schedule.

### **Do not try to make up for missed doses by taking more than one dose at a time.**

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

### *If you take too much (Overdose)*

**Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital if you think that you or anyone else may have taken too much PredMix Oral Liquid. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

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## While you are taking it

### *Things you must do*

**Take PredMix Oral Liquid exactly as your doctor has prescribed.**

If you do not follow your doctor's instructions you may not get improvement in the symptoms of your condition. Try not to miss any doses and take the medicine even if you feel well.

**Tell your doctor if your condition returns or becomes worse after your dose of PredMix Oral Liquid has been reduced or treatment has been stopped.**

**Tell your doctor immediately if you become pregnant while taking PredMix Oral Liquid.**

**Tell any other doctors, dentists and pharmacists who are treating you that you are taking PredMix Oral Liquid, especially if you are being started on any new medicines.**

**Tell your doctor, surgeon or dentist that you are taking PredMix Oral Liquid if you are about to undergo surgery or an operation.**

Your dose of this medicine may need to be increased to cover you during the stress of an operation.

**Tell your doctor straight away if you are a diabetic, and you notice a change in the results of your blood or urine sugar tests.**

This medicine may affect your blood sugar levels as it can affect the body's ability to handle glucose. For diabetics, this means that your diabetes may become more severe. For others, diabetes may develop for the first time while taking corticosteroids such as PredMix Oral Liquid.

**Ask your doctor when and how you should stop taking PredMix Oral Liquid.**

If you have been taking it for a long time your doctor may gradually reduce the amount you are taking over a period of several days, weeks or months before stopping completely.

If you have been taking PredMix Oral Liquid for a short period of time, this may not apply.

### *Things you must not do*

**Do not give this medicine to anyone else even if their symptoms seem similar to yours.**

**Do not stop taking PredMix Oral Liquid suddenly unless advised by your doctor.**

If you stop taking it suddenly, the symptoms of your condition may return or you may develop symptoms of cortisol deficiency such as fainting, weakness, restlessness, nausea, vomiting, headache, dizziness, muscle weakness or joint pain.

**Do not have any immunisations (particularly with "live" vaccines such as measles, oral polio or yellow fever) without your doctor's approval while you are being treated with PredMix Oral Liquid.**

### *Things to be careful of*

**Avoid close contact with anyone who has a contagious disease such as measles or chickenpox.**

Exposure to such diseases while you are taking this medicine, particularly if large doses are being taken, can put you at greater risk of developing these diseases if you have not had them before.

**Tell your doctor straight away if you think you have been exposed to chickenpox or measles.**

### *Things to be aware of*

As with any new medicine, you should take care when driving, operating machinery or drinking alcohol until you know how PredMix Oral Liquid affects you.

**Check with your doctor or pharmacist before drinking alcohol while you are taking this medicine.**

If you drink alcohol while taking it you may find that stomach problems occur.

The signs and symptoms of infections such as fever or inflammation may be hidden by the anti-inflammatory action of PredMix Oral Liquid. You should see your doctor for medical advice for any but the most minor infections.

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## Side effects

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking PredMix Oral Liquid.**

PredMix Oral Liquid helps most people who take it but it may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Ask your doctor or pharmacist to answer any questions you may have.**

### *Short term use*

When PredMix Oral Liquid is taken for short periods of time it is unlikely to cause any problems.

**Tell your doctor if you notice any of the following and they worry you:**

- mood changes
- nausea (feeling sick)
- vomiting
- anorexia (which may result in weight loss)
- increased appetite (which may result in weight gain)
- stomach bloating or irritation
- diarrhoea or constipation.

### *Long term use*

When PredMix Oral Liquid is taken for long periods of time and in high doses the risk of side effects is greater.

**Tell your doctor if you notice any of the following and they worry you:**

**general changes to the body:**

- bloating and rounding of the face (moon face)
- headache
- dizziness
- weight gain
- redistribution of body fat
- water retention leading to swollen legs and feet, high blood pressure or an irregular heartbeat
- cramps or weakness in the muscles of the arms and legs
- slowed growth in children
- irregular menstrual periods.

**changes to the skin:**

- acne
- red or flushed face
- extra hair growth
- red or purple streaks
- easy bruising
- skin thinning
- increased sweating
- poor wound healing.

**changes to the immune system:**

- an increased seriousness or frequency of infections.

**changes in behaviour:**

- excessive mood swings (such as changes in personality)
- anxiety or nervousness
- restlessness
- trouble sleeping.

**changes in eyes:**

- decreased or blurred vision
- eyes sticking out too far

- cataracts.

**Tell your doctor immediately or go to casualty at your nearest hospital if you notice any of the following symptoms:**

- severe stomach or intestinal pain
- epileptic fits
- sudden changes to your vision
- symptoms such as severe dizziness, fainting, weakness, chest pain or irregular heart beat
- psychiatric disturbances.

These are all serious side effects of PredMix Oral Liquid which may occur with high doses and long term use. You may need urgent medical attention or hospitalisation.

Some side effects can only be detected by your doctor. So it is important to visit your doctor for regular check-ups when PredMix Oral Liquid is taken for long periods of time.

Such side effects may include:

- osteoporosis or other changes in bone which can result in an increased chance of fractures due to brittleness or softening of the bone
- changes in other hormone levels in your body
- changes in the body's ability to handle glucose (steroid diabetes)
- effects on the parathyroid and thyroid glands which control calcium and body metabolism
- increased amounts of cholesterol in the blood
- changes to your white blood cells
- changes to your nervous system which may affect the way your nerves work
- changed sperm count
- increased blood pressure
- increased pressure in the skull.

**Tell your doctor if you notice anything else that is making you feel unwell.**

Some people may get other side effects while using PredMix Oral Liquid.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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## After taking it

### *Storage*

**Keep PredMix Oral Liquid in the container it came in, tightly closed.**

**Store it in the refrigerator (between 2° and 8°C). Do not freeze.**

**Discard 4 weeks after opening.**

**Keep it where young children cannot reach it.**

### *Disposal*

**If your doctor tells you to stop taking PredMix Oral Liquid, or you find that the expiry date has passed, ask your pharmacist what to do with any liquid you have left over.**

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## Product description

### *What it looks like*

PredMix Oral Liquid is a clear, colourless liquid. It is available in 30 mL bottles.

### *Ingredients*

PredMix Oral Liquid contains 7.06 mg/mL prednisolone sodium phosphate (equivalent

to 5 mg prednisolone) as the active ingredient.

It also contains the following inactive ingredients:

- disodium edetate
- methyl hydroxybenzoate
- propylene glycol
- propyl hydroxybenzoate
- dibasic sodium phosphate dodecahydrate
- monobasic sodium phosphate
- water - purified.

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## Sponsor

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