SONE

Prednisone (PRED-ni-sone)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SONE (prednisone tablets). It does not contain all the available information about SONE tablets. It does not replace talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you or your child taking SONE against the benefits he or she expects it will have.

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 is SONE

The name of your medicine is SONE and is available in 5 mg and 25 mg tablet strengths.

The active ingredient is called prednisone.

Prednisone belongs to a group of medicines called corticosteroids.

Corticosteroids are used to help reduce inflammation in your body or suppress your immune system, when a disease may be due to an auto-immune reaction (where your body fights against itself).

What SONE is used for

SONE is used to treat a number of medical conditions.

Your doctor will be able to help decide if SONE is suitable for your condition.

Ask your doctor if you have any questions about why SONE has been prescribed for you.

If you have any concerns, you should discuss this with your doctor.

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

Before you take SONE

When you must not take it

Do not take SONE if you are allergic to:

- Prednisone or other cortisone type medications, or any of the ingredients listed at the end of this leaflet including lactose monohydrate.

Some of the symptoms of an allergic reaction to SONE may include urticaria and other skin rashes, difficulty breathing, swelling of the face or throat or faintness.

Do not take SONE if you:

- have a peptic ulcer
- suffer from osteoporosis (brittle bones)
- have severe disturbances in thoughts, feelings and behaviours (psychoneuroses)
- have tuberculosis.

Do not take SONE if you are breastfeeding or plan to breast-feed.

Do not take SONE if you know you have any infections, including mumps, measles or chickenpox.

Do not use SONE after the expiry date (EXP.) printed on the pack.

If you take it after the expiry date has passed, it may have no effect at all, or worse, there may be an entirely unexpected effect.

Do not use SONE if the packaging is torn or shows any signs of tampering.

Do not give it to children, unless your doctor has prescribed it.

Before you start to take it

You must tell your doctor if:

1. **You are allergic to any other medicines or any foods, dyes or preservatives**
2. **You have or have had any other medical conditions or health problems, including:**
   - tuberculosis (TB)
   - a stomach ulcer
   - osteoporosis (brittle bone disease)
   - myasthenia gravis
   - congestive heart failure or have any other heart disease
   - diabetes
   - kidney failure
   - an underactive thyroid gland (hypothyroidism)
   - any infection (bacterial or fungal) including viral infections such as chicken pox
3. **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.

4. **Take Typhoid Vaccine.**

   Live or attenuated vaccines such as oral typhoid vaccine must not be taken with SONE.

5. **You are pregnant or plan to become pregnant.**

   SONE like all medicines should not be used during pregnancy, unless your doctor tells you.

6. **You are breastfeeding or plan to breastfeed.**

   SONE is expelled in breast milk and therefore should only be taken if your doctor tells you.

If you have not told your doctor about any of the above, tell them before you take any SONE.

Taking other medicines

Tell your doctor 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 SONE. These include:

- medicines used to treat upset stomachs such as antacids
- medicines used for diabetes including insulin
- medicines used to treat tuberculosis such as rifampicin
- medicines used to treat fungal infections such as ketoconazole
- some medicines which have a high sodium content and also foods with a high sodium content - check with your pharmacist
- some fluid reducing tablets, also called diuretics
- barbiturates, medicine used to treat epilepsy
- high doses of aspirin
- potassium supplements
- growth hormones
- digoxin or digitalis glycosides
- course of vaccinations

The above medicines may either reduce the effectiveness of SONE, reduce its own effectiveness and/or react with SONE resulting in untoward or sometimes dangerous side effects.

Tell your doctor if you are taking SONE tablets before you undergo any laboratory test. SONE may interfere with laboratory tests to check your thyroid.

Alcohol may interfere whilst you are taking SONE tablets.

This list is not exhaustive. Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking SONE.

How to take SONE

How much to take

Your doctor will decide the right dose for you.

The dose you need depends on your medical condition, the treatment you are undergoing and your response to it.

The recommended doses are for:

Adults: 10 mg to 100 mg daily in divided doses.

Children: 1 to 5 years: 2.5 mg to 10 mg twice daily.

Children: 6 to 12 years: 5 mg to 20 mg twice daily.

Follow your doctor's instructions carefully, if you need to reduce your dose of SONE.

High doses of SONE should be reduced gradually.

How to take it

Swallow the medicine with water. If the dose is one-half tablet, there is a break-line on the tablet to help you divide it.

When to take it

Take SONE after meals at the time directed by your doctor.

How long to take it

Continue taking SONE as long as your doctor recommends it.

If you forget to take it

If your dosing schedule is one dose a day, take the missed dose as soon as possible, but not later than 4 hours before your next dose. If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you are unsure about whether to take your next dose, speak to your doctor or pharmacist.

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

This may increase the chance of you getting an unwanted side effect.

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 the 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 SONE. Do this even if there are no signs of discomfort or poisoning. Also report any other medicine or alcohol which has been taken. You may need urgent medical attention.

Keep telephone numbers for these places handy.

If you take too much SONE you may have the following symptoms:

weakness, convulsions, dizziness, headache, nausea, vomiting, blurred vision, menstrual irregularities, and symptoms associated with electrolyte and fluid depletion and high blood pressure (hypertension).

While you are using SONE

Things you must do

Use SONE exactly as your doctor has prescribed.

Tell all doctors, dentists and pharmacists who are treating you that you are taking SONE.

Tell your doctor promptly if you become pregnant while you are taking SONE.

Tell your doctor if you feel SONE is not helping your condition.

Visit your doctor regularly.

Your doctor needs to check your progress and see whether you need to keep taking SONE.

Always discuss with your doctor any problems or difficulties during or after taking SONE.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

Keep enough SONE to last weekends and holidays.

Things you must not do

Do not take any other medicines while you are taking SONE without first telling your doctor.

Do not drive or operate machinery until you know how SONE affects you.

SONE may cause dizziness in some people and therefore may affect alertness.

Make sure you know how you react to SONE before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or have blurred vision.

Do not take SONE for a longer time than your doctor has prescribed.

Do not change your dose without first checking with your doctor.

Do not stop taking SONE or lower the dose, without first checking with your doctor.

Stopping this medicine suddenly on your own accord may cause some unwanted and dangerous effects, or your condition may reappear. Your doctor will advise you when you can stop taking SONE completely.

Do not use this medicine to treat any other complaints unless your doctor says to.

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking SONE.

SONE helps most people with medical conditions listed in the beginning of this leaflet, but it may have unwanted side effects in some people.

All medicines 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 any questions you may have.

Short term use

When Sone is taken for short periods of time it is unlikely to cause any problems.

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

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

Long term use

When Sone 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
- high blood pressure
- weight gain
- redistribution of body fat
- water retention leading to swollen legs and feet, high blood pressure or an irregular heart beat
- 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
- red or purple streaks
- easy bruising
- skin thinning
- increased sweating
- poor wound healing
- skin rashes.

Changes to the immune system:

- an increased seriousness or frequency of infections.

Changes in behaviour:

- excessive mood swings (such as changes in personality and loss of contact with reality)
- anxiety or nervousness
- depression
- euphoria

- restlessness
- trouble sleeping.

Changes in eyes:

- decreased or blurred vision
- eyes sticking out too far
- cataracts.

Side effects where the frequency is not known:

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.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following symptoms:

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

These are all serious side effects of Sone. 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 Sone is taken for long periods of time.

Such side effects can 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
- increased blood pressure
- increased pressure in the skull
- increased pressure in the eye (glaucoma)
- rare eye diseases such as central serous chorioretinopathy (CSCR).

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

Some people may get other side effects while using SONE.

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

Your doctor may lower the dose to help control serious side effects and decide on necessary tests to monitor any of the above problems.

Check with your doctor as soon as possible if you have any problems while taking SONE, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

After using SONE

Storage

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep SONE in a cool dry place where the temperature stays below 30°C and protect from light.

Do not store it, or any other medicines, in a bathroom or near a sink.

Do not leave it in the car or on windowsills.

Heat and dampness can destroy some medicines.

Do not take SONE if the tablets do not look quite right.

Keep your tablets in the bottle they were provided in until it is time to take them.

Disposal

If your doctor tells you to stop taking the tablets or they have passed their expiry date, ask your pharmacist what to do with any left over.

Product description

What it looks like

SONE 5 mg tablet is a white round plain uncoated tablet, one side plain and the other scored. It comes in a bottle of 60 tablets.

SONE 25 mg tablet is a white round plain uncoated tablet, one side plain and the other scored. It comes in a bottle of 30 tablets.

Ingredients

Each SONE 5 mg tablet contains 5 mg of the active ingredient, prednisone.

The other ingredients are:

- lactose monohydrate
- propyl hydroxybenzoate
- maize starch
- wheat starch
- gelatin
- magnesium stearate

Each SONE 25 mg tablet contains 25 mg of the active ingredient, prednisone.

The other ingredients are:

- lactose monohydrate
- propyl hydroxybenzoate
- maize starch
- wheat starch
- gelatin
- magnesium stearate

SONE contains lactose and gluten but does not contain sucrose.

Sponsor

iNova Pharmaceuticals (Australia) Pty Limited

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Telephone: 1800 630 056

The Australian Registration Number for SONE 5 mg tablet is

AUST R 56129.

The Australian Registration Number for SONE 25 mg tablet is

AUST R 13470.

This leaflet was prepared in August 2018.