

Sinequan® Capsules

Doxepin hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Sinequan. It does not contain all the available information.

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 Sinequan against the benefits it is expected to have for you.

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

Read this leaflet carefully before you start Sinequan and keep it with the medicine.

You may need to read it again.

What Sinequan is used for

Sinequan is used to treat depression.

It belongs to a group of medicines called tricyclic antidepressants (TCAs).

Antidepressants are thought to work by their action on brain chemicals called amines which are involved in controlling mood.

Your doctor, however, may prescribe Sinequan for another purpose.

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

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

Sinequan should not be used in children under the age of 18 years.

The safety and efficacy of Sinequan in this age group has not been satisfactorily established.

Before you take Sinequan

When you must not take it

Do not take Sinequan if you have an allergy to:

- any medicine containing doxepin hydrochloride
- any other tricyclic antidepressant
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to Sinequan may include:

- shortness of breath
- wheezing or difficulty breathing
- skin rash, itching or hives on the skin
- swelling of the face, lips, tongue or other parts of the body
- increased sensitivity of the skin to the sun.

Do not take Sinequan if you are taking a medicine called a monoamine oxidase inhibitor (MAOI) or have been taking it within the last 14 days.

Taking Sinequan with a MAOI may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and convulsions.

Ask your doctor or pharmacist if you are not sure if you are taking or have been taking a MAOI.

MAOIs are medicines used to treat depression and symptoms of Parkinson's Disease. Examples of

MAOIs are phenelzine (Nardil), tranylcypromine (Parnate), moclobemide (e.g. Aurorix) and selegiline (e.g. Eldepryl).

Do not take Sinequan if you are breastfeeding unless directed by your doctor.

Like many other medicines, Sinequan can pass into breast milk and may affect your baby.

Do not take Sinequan if you have:

- glaucoma, a condition where the pressure in the eye is increased, including a type of glaucoma called angle closure glaucoma
- urinary retention (difficulty in passing urine).

If you are not sure if you should be taking Sinequan, talk to your doctor.

Do not take Sinequan if the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

You must tell your doctor if you are allergic to:

- any other medicines
- any other substances such as foods, dyes or preservatives.

Tell your doctor if you are not well or have any other health problems or history of, including:

- any mental illness
- heart disease
- liver or kidney problems
- diabetes.

Tell your doctor if you are pregnant or intend becoming pregnant.

Your doctor will discuss the risks and benefits of taking Sinequan during pregnancy.

If you have not told your doctor or pharmacist about these things, tell them before you start taking Sinequan.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including:

- all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may be affected by Sinequan or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

Tell your doctor or pharmacist if you are taking any of the following:

- monoamine oxidase inhibitors (MAOIs), medicines used for the treatment of depression.

Taking Sinequan with, or within 14 days of stopping a MAOI may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and convulsions.

Wait at least 14 days after stopping your MAOI before starting Sinequan.

- other medicines for depression (Tofranil, Pertofran, Prozac, Aropax, Zolofl)
- cimetidine (e.g. Tagamet)
- medicines for diabetes (e.g. Rastinon, Daonil, Diabinese, Minidiab)
- anti-anxiety medicines (e.g. Diazepam, Valium, Ducene, Serepax, Tranxene)

- medicines containing atropine (e.g. Atropt, Atropine eye drops, Atropine Sulphate injection) or medicines for irritable bowel syndrome (e.g. Probanthine, Buscopan)
- tranquillisers such as Risperdal, Melleril, Modecate or Largactil
- medicines for controlling abnormal heart beats (e.g. Kinidin Durules, Tambocor)
- medicines for epilepsy (e.g. Dilantin, Tegretol)
- medicines containing adrenaline or noradrenaline (e.g. nasal drops, decongestants, some cough mixtures, some local anaesthetics)
- stimulant medicines containing amphetamine (e.g. Dexamphetamine)
- guanethidine (e.g. Ismelin).

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Sinequan.

How to take Sinequan

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

They may differ from the information in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

The dose of Sinequan varies from 30 to 300 mg daily.

Your doctor will decide the right dose for you. This depends on your condition, age, whether or not you are taking any other medicines, and how you respond to Sinequan.

It is usual to start with a low dose and then, if necessary, increase it gradually until the right dose is reached.

How to take it

Swallow the capsules with a glass of water or other liquid.

When to take it

Sinequan can be taken with or without food.

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it

Keep taking Sinequan until your doctor tells you to stop.

Most antidepressants take time to work so do not be discouraged if you do not feel better straight away. It may take 2 to 3 weeks to feel the full benefit of Sinequan.

Even when you feel well, you may need to take Sinequan for several months or longer to make sure that the benefits last.

Do not stop taking Sinequan, or change the dose, without first checking with your doctor.

If you forget to take it

If it is almost time for your next dose (e.g. within 2 or 3 hours), skip the dose you missed and take your next dose when you are meant to.

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

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 are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering 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), or go

to Accident and Emergency at your nearest hospital if you think you or anyone else may have taken too much Sinequan. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include:

- shortness of breath
- feeling drowsy
- fast or irregular heartbeats
- feeling agitated
- fever.

While you are taking it

Things you must do

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

If you are about to start any new medicine, tell your doctor and pharmacist that you are taking Sinequan.

If you become pregnant while taking Sinequan, tell your doctor immediately.

If you are a woman of childbearing age, you should avoid becoming pregnant while taking Sinequan.

Tell your doctor immediately if you have any suicidal thoughts or other mental/mood changes.

If you or someone you know is demonstrating any of the following warning signs of suicide while taking Sinequan, contact your doctor or a mental health professional right away or go to the nearest hospital for treatment:

- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts of self-harm
- increase in aggressive behaviour, irritability or agitation
- worsening of depression.

Occasionally, the symptoms of depression may include thoughts of suicide or self-harm. These symptoms may continue or get worse during the first one to two months of treatment until the full antidepressant effect of the medicine becomes apparent. This is more likely to occur in young adults under 24 years of age.

All mentions of suicide or violence must be taken seriously.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

Your doctor may ask you to stop taking Sinequan a few days before surgery.

Things you must not do

Do not stop taking Sinequan, or change the dose, without first checking with your doctor.

Do not let yourself run out of capsules over the weekend or on holidays.

Suddenly stopping Sinequan may make you feel tired, sick in the stomach and give you a headache. To prevent this, your doctor may want to gradually reduce the amount you take each day before stopping the medicine completely.

Do not give Sinequan to anyone else, even if they have the same condition as you.

Do not take Sinequan to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how Sinequan affects you.

Sinequan may cause drowsiness and affect co-ordination in some people.

If this occurs, do not drive, operate machinery or do things that may be dangerous if you are not alert.

Be careful when drinking alcohol while taking Sinequan.

Combining Sinequan and alcohol can make you more sleepy, dizzy or lightheaded.

Your doctor may suggest you avoid alcohol while you are being treated for depression.

All of the above precautions are important even after you have stopped taking Sinequan.

The effects of Sinequan may last for some days after you have stopped taking it.

Side effects

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

It can be difficult to tell whether side effects are the result of taking Sinequan, effects of your condition or side effects of other medicines you may be taking. For this reason it is important to tell your doctor of any change in your condition.

Do not be alarmed by the list of side effects.

You may not experience any of them.

Ask your doctor or pharmacist any questions you may have.

Tell your doctor if...

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

- drowsiness, dizziness, lightheadedness
- difficulty in sleeping, bad dreams
- dry mouth
- blurred vision
- difficulty in passing urine
- feeling sick, vomiting, indigestion
- diarrhoea, constipation
- changes in taste, or taste sensitivity

- loss of appetite or increase in appetite
- mouth ulcers
- numbness.

These side effects are usually mild.

Tell your doctor as soon as possible if...

Tell your doctor as soon as possible if you notice any of the following:

- anxiety, nervousness, aggressive behaviour
- fast or irregular heart beat
- chest pain
- bleeding or bruising more easily than normal, reddish or purple blotches under the skin
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- yellowing of the skin and eyes (also called jaundice)
- agitation, confusion
- symptoms of tiredness, abdominal pain, jaundice and history of gallstones
- symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal
- unsteadiness, stiffness, shakiness or unwanted movements.

Go to hospital if...

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

- seizures or fits
- symptoms of high fever, drowsiness, sweating, fast heart beat and muscle stiffness
- symptoms of allergy such as a skin rash, increased sweating, swelling of the face or tongue
- thoughts of suicide or attempting suicide or self harm
- sudden pain or ache in or around your eye

- eyes becoming red, or feeling hard or tender
- vision worsening, becoming blurred or starting to see circles (haloes) around lights.

These symptoms are usually rare but may be serious and need urgent medical attention.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Other side effects not listed above may occur in some people.

Some of these side effects (e.g., changes in blood pressure, liver function or glucose control) can only be found when your doctor does tests from time to time to check your progress.

After taking Sinequan

Storage

Keep your capsules where children cannot reach them.

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

Keep Sinequan in a cool, dry place where the temperature stays below 25°C. Do not store it, or any other medicine, in the bathroom or near a sink. Do not leave it in the car or on window sills. Protect from light.

Heat and dampness can destroy some medicines.

Keep your capsules in their blister pack until it is time to take them.

If you take the capsules out of their container they may not keep well.

Disposal

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

Product description

What it looks like

Sinequan capsules come in two strengths:

- Sinequan 10 mg - natural, size #4 capsules printed with "Sinequan 10" and the Pfizer logo.
- Sinequan 25 mg - natural, size #4 capsules printed with "Sinequan 25" and the Pfizer logo.

Each pack contains 50 capsules.

Ingredients

The active ingredient in Sinequan is doxepin hydrochloride.

- Sinequan 10 mg - 10 mg doxepin per capsule
- Sinequan 25 mg - 25 mg doxepin per capsule

The capsules also contain lactose, maize starch, magnesium stearate, sodium lauryl sulfate, gelatin and the colouring agent within the printing ink, TekPrint SW-9008 Black Ink (PI 2328).

Supplier

Sinequan is supplied in Australia by:

Pfizer Australia Pty Limited
Sydney NSW
Australia.

Toll Free number: 1800 675 229.
www.pfizer.com.au

Australian Registration Number

Sinequan 10 mg - AUST R 10767

Sinequan 25 mg - AUST R 302563

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