

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S5**

PROPRIETARY NAME AND DOSAGE FORM

STILPANE

Tablets

Read all of this leaflet carefully before you start taking **STILPANE**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- STILPANE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT STILPANE CONTAINS

The active ingredients in each STILPANE tablet are:

Meprobamate	150 mg
Codeine phosphate	8 mg
Paracetamol	320 mg
Caffeine anhydrous	32 mg

Excipients:

The other ingredients are dye lake green (C.I No's: 47005, 42090, 15985), magnesium stearate, nipastat, povidone K25, sodium starch glycollate, starch, talc.

Preservative:

Nipastat	0,02 % <i>m/m</i>
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Sugar free

WHAT STILPANE IS USED FOR

STILPANE is indicated for short term use (no longer than 5 days) in mild to moderate pain associated with anxiety or tension.

BEFORE YOU TAKE STILPANE

Do not take STILPANE

- If you are hypersensitive (allergic) to any of the ingredients in STILPANE.
- If you are pregnant or breastfeeding.
- If you have porphyria (a disorder relating to the pigment of blood).
- If you have severe liver, kidney or lung problems.
- If you have asthma, bronchitis or breathing problems.
- If you have just had an operation on your bile tract.
- If you are an alcoholic.
- If you have had a recent head injury or if you have a condition in which the pressure in your skull is increased.
- During an asthma attack.
- If you have heart failure caused by chronic lung disease.
- If you are using monoamine oxidase inhibitors (usually used to treat depression) or within fourteen days of stopping such treatment.

Take special care with STILPANE

- If more tablets than recommended are taken or if used for a longer period of time than recommended, STILPANE may lead to dependency and addiction.
- Even if taken at normal doses, STILPANE can cause increased morphine (active

metabolite of codeine) levels which may produce clinical signs of morphine intoxication.

Paracetamol

Taking higher doses of paracetamol than recommended may cause severe liver damage.

STILPANE use for a period longer than recommended can cause irreversible kidney damage. STILPANE should not be used for periods longer than 5 days. Patients suffering from liver or kidney disease should take STILPANE under medical supervision. Consult your doctor if no relief is obtained from the recommended dosage. STILPANE should be given with care to patients taking other medicines that affect the liver, e.g. barbiturates (used to treat epilepsy).

Codeine phosphate

Codeine should be given with caution to patients with:

- under active thyroid gland (a condition where the thyroid gland does not produce enough hormones)
- adrenocortical insufficiency (a condition where the adrenal glands do not produce enough steroid hormone)
- asthma
- impaired liver function
- enlarged prostate gland
- low blood pressure
- shock (a condition where there is not enough blood flow through the body)
- inflammatory or obstructive bowel disorders (a problem or blockage of your bowel)
- diseases or conditions that cause weakness of muscles around the eyes, mouth and throat.

STILPANE should be avoided in the elderly and debilitated (very weak or sick) patients.

STILPANE administration during labour may cause breathing problems in the new-born infant.

Codeine may cause a decrease in the function and activity of the brain. This effect may be increased by medicines that slow down brain activity such as alcohol, anaesthetics, calming and sleeping tablets, and phenothiazines. The prolonged use of high doses of codeine has produced addiction similar to morphine addiction.

Caffeine anhydrous

Extremely high doses and increased sensitivity to STILPANE may lead to agitation, increased urine, repeated vomiting with extreme thirst, disorientation (confusion), hallucinations, very high body temperature (41 °C or above), abnormal heartbeat including increased heart rate, electrolyte disturbances, convulsions and death.

STILPANE should be given with caution to patients with:

- peptic ulcer (sores in the stomach or intestine)
- over active thyroid gland (a condition where the thyroid gland produces more hormones than needed)
- high blood pressure
- epilepsy (a brain disorder causing seizures)
- abnormal heartbeat or other diseases involving the heart or blood vessels as these conditions may worsen
- alcoholics
- acute fever
- newborn babies and the elderly

Meprobamate

STILPANE should be avoided in elderly and debilitated (very sick or weak) patients and in those with mental depression. STILPANE may cause convulsion (uncontrolled shaking of the body) in patients with a history of epilepsy.

STILPANE should be used with caution in patients with:

- reduced liver or kidney function
- reduced lung functions.

There is a serious addiction risk with a typical withdrawal syndrome. STILPANE should not be used for the stress of daily living. Using alcohol with STILPANE may lead to reduced judgment and coordination.

Pregnancy and breastfeeding

Do not use STILPANE when you are pregnant or breastfeeding your baby as safety has not been established.

If you are pregnant or breastfeeding, please consult your doctor, pharmacist or other healthcare provider for advice before taking STILPANE.

Driving and using machinery

Do not drive or operate machinery, because the use of STILPANE may lead to drowsiness and impaired concentration that may be aggravated by the simultaneous intake of alcohol or anti-depressants.

Taking other medicines with STILPANE

Always tell your healthcare provider if you are taking any other medicines (this includes complementary or traditional medicines).

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

- Alcohol,
- mexiletine,
- antibiotics (e.g. ciprofloxacin, enoxacin and pipemidic acid),
- isoniazid,
- anti-depressants (e.g. fluvoxamine, monoamine oxidase inhibitors and tricyclic anti-depressants),
- anti-epileptics (e.g. phenytoin, carbamazepine, phenobarbital, primidone and lamotrigine),
- gastrointestinal medicines (e.g. cimetidine),
- lithium,
- methoxsalen,
- oral contraceptives,
- sympathomimetics (e.g. phenylpropanolamine),
- metoclopramide,
- probenecid,
- cholestyramine,
- anti-coagulants (e.g. warfarin),
- anti-virals (e.g. interferon alfa and zidovudine),
- phenothiazines,
- anti-histamines (e.g. hydroxyzine).

HOW TO TAKE STILPANE

Do not share medicines prescribed for you with any other person.

For short term use only. Do not use STILPANE for longer than 5 days.

STILPANE should not be used in children under 12 years of age.

The usual dose is:

Take two tablets orally three or four times a day as required.

DO NOT EXCEED THE RECOMMENDED DOSE.

Your doctor will tell you how long your treatment with STILPANE will last.

Always take STILPANE exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of STILPANE is too strong or too weak, talk to your doctor or pharmacist.

If you take more STILPANE than you should

In the event of overdose, consult a doctor or pharmacist immediately. If neither is available, seek help at the nearest hospital or poison center. Prompt treatment is essential. Evidence of liver damage is often delayed until after the time for effective treatment has lapsed. Symptoms of paracetamol overdose in the first 24 hours are pallor, nausea, vomiting, anorexia and possibly abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormal heart beat has been reported.

Overdose with STILPANE can cause severe and/or fatal low blood pressure, respiratory depression, shock, heart failure and death.

POSSIBLE SIDE EFFECTS

STILPANE can have side effects.

Not all side effects reported for STILPANE are included in this leaflet. Should your general health worsen while taking STILPANE or if you notice any side effects not mentioned in this

leaflet, please inform your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking STILPANE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Sensitivity reactions: medicine fever and abscesses/ulcers, allergic skin condition, itching of the nose and medicine sensitivity, bleeding skin rash, swelling of the lips, eyes or tongue.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to STILPANE. You may need urgent medical attention or hospitalisation.

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

- Hallucinations;
- convulsions;
- deepening coma;
- raised skull pressure;
- decreased or increased heartbeat;
- decreased white and red blood cells;
- decreased blood platelets;
- blood cell production disorder.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

The following side effects have been frequently reported:

- Drowsiness;

- insomnia;
- headache;
- anxiety, restlessness;
- unsteady, shaky movements;
- constipation, nausea, vomiting, abdominal pain.

The following side effects have been reported less frequently:

- Difficulty in urination;
- muscle rigidity;
- sensitivity reaction: red skin rash, itchy rash, sweating;
- light headedness when standing up;
- facial flushing;
- confusion, mood changes;
- pupil (eye) contraction;
- sleepiness, dizziness, faintness;
- excitement, cheerfulness;
- weakness;
- headache;
- dry mouth;
- gastrointestinal bleeding;
- diarrhoea;
- disturbance of vision.

The following side effects have been reported but the frequency is unknown:

- Low blood pressure;
- balance disorder;
- reduced body temperature;

- tremor;
- pins and needles sensation.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORAGE AND DISPOSING OF STILPANE

Store at or below 25 °C, in a well-closed container.

Protect from light.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF STILPANE

100 tablets are packed in aluminium/PVC blister strips. The strips are packed, together with a leaflet into a unit carton.

500 tablets are packed into a white polypropylene (PP) securitainer, together with a foam insert and a leaflet and sealed with a white polyethylene cap.

1 000 tablets are packed into amber PVC jars together with a foam insert and a leaflet and sealed with a screwcap.

Not all packs and pack sizes are necessarily marketed.

IDENTIFICATION OF STILPANE

Green, biconvex tablet, debossed "C26" on the one side and bisected on the other side.

REGISTRATION NUMBER

M/2.9/2

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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