

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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# SINTROM

4mg Tablets

ACENOCOUMAROL

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• 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 •*

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### What is in this leaflet?

1. What SINTROM is and what it is used for
2. Before you take SINTROM
3. How to take SINTROM
4. Possible side effects
5. How to store SINTROM
6. Further information

#### *1. WHAT SINTROM IS AND WHAT IS IT USED FOR*

SINTROM belongs to a group of medicines called anticoagulants (blood thinning medicines).

SINTROM is used to treat and prevent blood clots blocking the blood vessels e.g. deep vein thrombosis (DVT). SINTROM does not dissolve blood clots that have already formed but it may stop the clots from becoming larger and causing more serious problems.

#### *2. BEFORE YOU TAKE SINTROM*

Follow all the doctor's instructions carefully. They may differ from the general information contained in this leaflet.

#### **Do not take SINTROM:**

- if you are allergic (hypersensitive) to acenocoumarol, any other medicines that you have taken to thin your blood or to any of the ingredients in

SINTROM

- if you are pregnant, planning to become pregnant or breast-feeding
- if you are an alcoholic
- if you have any mental illness for example, schizophrenia or dementia
- if you have recently had, or are about to have an operation on your spine,

brain, eyes or any major surgery

- if you have had a stroke caused by bleeding into your brain
- if you suffer from very high blood pressure
- if you have a stomach ulcer or any intestinal bleeding
- if you pass blood in your water or cough up blood
- if you suffer from any bleeding disorders, bleeding problems or

unexplained bruising

- if you have pericarditis or endocarditis – inflammation or infection around the heart which causes pain in the chest
- if you have severe liver or kidney disease
- if you regularly drink cranberry juice or take cranberry extracts.

If any of the above applies to you, or if you are not sure, speak to your doctor or pharmacist before you take SINTROM.

### ***Take special care with SINTROM***

Before you take SINTROM tell your doctor or pharmacist:

- if you have cancer
- if you have an infection or inflammation (swelling)
- if you have a disorder affecting the absorption of food from the stomach and/or intestine
- if you have heart failure (which causes swelling and shortness of breath)
- if you have liver or kidney problems
- if you have an overactive thyroid
- if you are elderly
- if you suffer from a blood disorder such as protein C or protein S deficiency
  - this would cause you to bleed for longer than normal after a cut or injury.

You should not receive any injections into your muscles whilst you are taking SINTROM.

If you need any injections into your spine or as part of a scan or X-ray test or

if you need minor surgery, including dental surgery, make sure you discuss your treatment with your doctor first.

If you are involved in an accident while on SINTROM you are likely to bleed more than normal. The doctor or hospital staff must be informed that you are taking SINTROM immediately. Always carry your personal anticoagulation card (an identification card from your pharmacist stating that you are using this medicine).

If any of the above applies to you, or if you are not sure, speak to your doctor or pharmacist before you take SINTROM.

### ***Taking other medicines***

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription (over-the-counter). This applies especially to the following medicines as they may interfere with SINTROM:

#### ***Medicines that increase the activity of SINTROM such as:***

- heparin - to thin the blood in the treatment of deep vein thrombosis, blood clots or after surgery

- Salicylic acid and related substances (e.g. Acetyl salicylic acid, aminosalicic acid, diflunisal) (medicine used against pain)
- Clopidogrel, ticlopidine, phenylbutazone or other pyrazolone derivatives (sulfapyrazone), other non-steroidal anti-inflammatory agents (medicines affecting the function of platelets (particles in the blood involved in blood clotting)).

When SINTROM is prescribed in combination with these drugs, more frequent monitoring (including blood tests) will be needed.

***Other medicines that may increase the activity of SINTROM such as:***

- allopurinol or sulfapyrazone - for the treatment of gout and to lower uric acid levels
- anabolic steroids - used as replacement therapy
- androgens such as testosterone and mesterolone - used as replacement therapy
- anti-arrhythmic agents such as amiodarone and quinidine - medicines for an irregular heartbeat
- antibiotics (e.g. erythromycin, tetracyclines, neomycin, chloramphenicol, amoxicillin, some cephalosporins, some fluoroquinolones)- medicines used against infections
- selective serotonin re-uptake inhibitors such as fluoxetine and paroxetine - used to treat anxiety and depression
- paracetamol – a medicine used for pain
- sulfonamides such as co-trimoxazole - used to treat infections
- sulphonylureas such as tolbutamide, chlorpropamide and glibenclamide - oral medicines for diabetes
- thyroid hormones such as levothyroxine - used to treat an underactive thyroid
- statins and other lipid lowering drugs such as fenofibrate, simvastatin or colestyramine - used to lower blood cholesterol levels
- antineoplastics such as mercaptopurine and 5-fluorouracil - for breast, gastrointestinal and skin cancer
- H2-agonists such as cimetidine or ranitidine - used to treat stomach or intestinal ulcers
- clofibrate and related substances - medicines used against high cholesterol
- corticosteroids such as prednisolone and methylprednisolone - steroids used to treat inflammatory bowel disease, arthritis and certain skin conditions
- disulfiram - for alcohol dependence
- etacrynic acid or thiazide diuretics (“water tablets”) such as bendroflumethiazide or metolazone - for water retention or high blood pressure
- glucagon - used to treat low blood sugar levels
- imidazole derivatives (e.g. metronidazole, and even when administered locally, miconazole) - a medicine used against infection
- tramadol - a strong pain killer
- tamoxifen - for breast cancer and fertility
- azathioprine - for organ transplantation, chronic inflammatory and autoimmune diseases
- proton pump inhibitors (e.g. omeprazole)
- plasminogen activators (e.g. urokinase; streptokinase and alteplase, thrombin inhibitors (e.g. argatroben) - medicines used to breakdown blood clots during heart stroke
- prokinetic agents (e.g. cisapride) - medicines used against HIV disease
- antacids (e.g. magnesium hydroxide) and viloxazine - medicine used against stomach acidity.

**Medicines that may decrease the effect of SINTROM such as:**

- aminoglutethimide - used to treat cancer or Cushing's Syndrome
- protease inhibitors such as ritonavir or indinavir - used to treat HIV
- barbiturates such as sodium amytalbor Phenobarbital and carbamazepine
  - for epilepsy or to help you sleep
- corticosteroids (high-dose intravenous methylprednisolone, prednisolone) - medicines used to treat inflammation
- oral contraceptives such as Femodene, Logynon and Cilest- birth control
- rifampicin - medicine used against infection
- St John's Wort - for depression
- cholestyramine - medicine used against high cholesterol levels
- griseofulvin - used to treat fungal infections

**Effects of SINTROM on other medicines**

- SINTROM may increase the risk of toxicity by hydantoin derivatives such as phenytoin - medicines used to treat epilepsy

**Taking with food and drink**

Be careful when drinking alcohol as it may affect how SINTROM thins your blood. Check with your doctor first.

You should avoid drinking cranberry juice or taking other cranberry products, such as capsules or concentrates as this could mean you do not receive the correct amount of acenocoumarol.

**Elderly**

If you are 65 years or older you may be more sensitive to the effects of SINTROM and so need more frequent check-ups. You may also need lower doses.

**Children and adolescents**

Experience with SINTROM in children and adolescents is limited and so these patients need more frequent check-ups.

**Pregnancy and breast-feeding**

Do not take SINTROM if you are pregnant. SINTROM, like other anticoagulants can cause serious harm to your baby. Tell your doctor if you are pregnant or trying to become pregnant. Your doctor will discuss with you the potential risk of taking SINTROM during pregnancy.

The decision to breast-feed while taking SINTROM should be carefully considered with your doctor. You and your child may require blood tests if you are breast-feeding while you are taking SINTROM. However, as a precaution, your doctor should prescribe vitamin K to your child to prevent their blood from being thinned.

If you are of child bearing age, a pregnancy test may be done by your doctor to rule out pregnancy before you are given SINTROM.

You may also be asked to use birth control while taking SINTROM. Ask your doctor or pharmacist for advice before taking any medicine.

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

SINTROM has no influence on the ability to drive or use machines.

SINTROM tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor or pharmacist before taking this medicinal product.

### ***3. HOW TO TAKE SINTROM***

Always take SINTROM exactly as your doctor has told you to. You should check with your doctor or pharmacist if you are not sure.

SINTROM should be taken as a single dose at the same time every day. Swallow your tablets whole with a drink of water.

Your doctor will arrange regular blood tests during treatment with SINTROM to check on how fast your blood is clotting. This will help the doctor decide on your dose.

The dose of SINTROM will vary from patient to patient and from day to day. The following can be used as a guide:

#### **Adults and elderly:**

The usual starting dose is between 2 mg/day to 4 mg/day without administration of a loading dose. Treatment can be started with a loading dose regimen, usually 6 mg on the first day followed by 4 mg on the second day.

Elderly patients, patients with liver disease or severe heart failure or mal-nourished patients may need lower doses.

#### **Children:**

SINTROM is not recommended for children.

Tell your doctor or dentist or pharmacist at every visit that you are using SINTROM.

#### ***What to do if you take more SINTROM than you should***

If you accidentally take too many tablets, or someone else takes any of your medicine, you should tell your doctor immediately or contact the nearest accident and emergency department. You may require blood tests to monitor your condition and treatment may be required. Show any left-over medicines or the empty packet to the doctor.

#### ***If you forget to take SINTROM***

Do not worry. If you forget to take a dose, take it as soon as possible, unless it is almost time to take the next dose. Do not take a double dose. Then go on as before. If you have any questions about stopping SINTROM, talk to your doctor.

#### 4. POSSIBLE SIDE EFFECTS

If you get any of the following, tell your doctor or pharmacist:

**Common (may affect up to 1 in 10 people):**

Unusual bleeding such as:

- bleeding from the gums
- unexplained bruising or nosebleeds
- heavy periods
- heavy bleeding from cuts or wounds

Signs of bleeding inside the body such as:

- stomach or abdominal pain
- backache
- blood in the urine
- bloody or black tarry stools
- coughing or vomiting blood
- dizziness
- severe headache
- joint pain or stiffness
- blurred sight.

**Rare (may affect up to 1 in 1000):**

- allergic reaction in the form of skin rash, or itching
- skin rashes
- itching
- unexplained fever
- loss of appetite
- feeling or being sick
- unusual hair loss.

**Very rare (may affect up to 1 in 10,000):**

- bruising with blistering of the skin with or without scars, usually in areas of:
  - thighs
  - buttocks
  - abdomen
  - breast
  - or sometimes in the toes
- bruising or bleeding under the skin (possible sign of vasculitis)
- jaundice (possible signs of liver injury).

Tell your doctor or pharmacist if you think you have any of these or other problems with SINTROM:

***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.

By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. HOW TO STORE SINTROM

Keep out of the sight and reach of children.

Do not take SINTROM after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

If your doctor decides to stop your treatment, return any unused medicine to the pharmacist. Only keep it if your doctor tells you to.

If your tablets show any sign of deterioration or discolouration, consult your pharmacist for advice.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist on how to dispose of medicines no longer required. These measures will help protect the environment.

If you have any questions or are not sure about anything, ask your doctor or pharmacist. They will have additional information about this medicine and will be able to help you.

## 6. FURTHER INFORMATION

### **What SINTROM contains**

The active ingredient in this medicine is acenocoumarol. This is the new name for nicoumalone. The ingredient itself has not changed.

The other ingredients are lactose, hypromellose, magnesium stearate, maize starch, talc and silicon dioxide.

### **What SINTROM looks like and contents of the pack**

SINTROM are white, round, flat tablets, with slightly bevelled edges, with one side bearing the imprint "CG" and the other imprint "AA". They come in cartons of 60 & 100 tablets.

### **Manufacturer and licence holder**

This medicine is manufactured by Novartis Farmaceutica S.A, Gran Via de les Corts Catalanes, 764 08013 Barcelona, Spain and is procured from within the EU. Product licence holder LTT Pharma Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.