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This leaflet answers some common questions about **CERUVIN**.

It does not contain all of 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 **CERUVIN** against the benefits it is expected to 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 **CERUVIN** is used for

CERUVIN is used to prevent blood clots forming in hardened blood vessels (a process known as atherothrombosis) which can lead to events such as stroke, heart attack or death.

You may have been prescribed **CERUVIN** to help prevent blood clots forming and to reduce the risk of stroke, heart attack and death because:

- You have previously suffered a heart attack, stroke or have a condition known as peripheral arterial disease (leg pain on walking or at rest).
- You have suffered Acute Coronary Syndrome (either a severe type of chest pain called unstable angina, or a heart attack). In this you may also be prescribed aspirin.

Ask your doctor if you have any questions about why **CERUVIN** have been prescribed for you.

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

How **CERUVIN** works

CERUVIN contains Clopidogrel and belongs to a group of medicines called antiplatelet.

Antiplatelets work by helping to prevent harmful blood clots.

Platelets are very small structures in the blood which clump together during blood clotting. **CERUVIN** prevents this clumping and hence reduce the chances of blood clots formation.

Before you use **CERUVIN**

When you must not use it

Do not use **CERUVIN**

- If you are allergic to clopidogrel

Some of the symptoms of an allergic reaction may include:

Shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue, or other parts of the body, rash, itching or hives on the skin

- If you have a medical condition that is causing bleeding such as a stomach ulcer or bleeding within your head.
- If you suffer from severe liver disease.
- If you are breast-feeding or intend to breast-feed.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

The expiry date refers to the last day of that month. If it has expired or is damaged; return it to your pharmacist for disposal.

If you are not sure whether you should start taking **CERUVIN**, talk to your doctor or pharmacist.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

- You are planning to have an operation. Your doctor will stop **CERUVIN** 7 days prior to surgery
- If you have any medical conditions which increase the risk of blood loss from trauma, surgery or other pathological conditions such as,
 - bleeding disorders or blood clotting problems
 - recent serious injury
 - recent surgery
 - any form of liver or kidney disease
 - lesions with a propensity to bleed (such as ulcers).

If you have not told your doctor about any of the above, tell them before you start taking **CERUVIN.**

Pregnancy and breast-feeding

You should not take **CERUVIN** if

- You are pregnant or intend to become pregnant.
- You are breast-feeding or intend to breast-feed.
CERUVIN passes into breast milk and, therefore, there is the possibility that the breast-fed baby may be affected.

Some patients may not convert **CERUVIN** to its active form as well as other patients. These patients may not get the same benefit from **CERUVIN**. Your doctor may advise you to go for tests to determine if **CERUVIN** will adequately work for you. Based on the test results, your doctor may change your dose of **CERUVIN** or consider alternative treatments for you.

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 and **CERUVIN** may interfere with each other. These include:

- Aspirin, heparins and warfarin- medicines that thin the blood.
- Non-steroidal anti-inflammatory drugs (NSAIDs) - medicines used to treat arthritis, period pain, aches and pains.
- Phenytoin - a medicine used to treat epilepsy (fits).
- Tolbutamide - a medicine used to treat diabetes (sugar diabetes).
- Tamoxifen - a medicine used to treat breast cancer.
- Fluvastatin - a medicine used to lower cholesterol.
- Torsemide- a medicine used to reduce the swelling and fluid retention
- Thrombolytics eg. alteplase, reteplase- medicine used to dissolve blood clots
- Glycoprotein IIb/IIIa inhibitors eg. abciximab, eptifibatide- medicines used to reduce blood clots
- Medicine that inhibit an enzyme in our body called, CYP2C19 (eg. Proton pump inhibitors)- medicines used in treatment of ulcers

How to use CERUVIN

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

They may differ from the information contained in this leaflet.

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

How much to use

Your doctor will tell you how many **CERUVIN** tablets you should take. The dose your doctor will prescribe for you will be as follows:

The usual dose of **CERUVIN** is 75 mg daily.

If you have experienced severe chest pain (Acute Coronary Syndrome), you may receive a starting dose of 300 mg (4 tablets of 75 mg), then 75 mg daily.

CERUVIN is not intended for use in children or adolescents.

Kidney problems

No dosage adjustment is required.

How to use it

CERUVIN should be swallowed whole with a glass of water.

When to use it

CERUVIN should be taken once a day as advised by your doctor.

Take your prescribed dose at the same time each day.

CERUVIN can be taken with or without food.

How long to use it

You should take **CERUVIN** for as long as your doctor continues to prescribe it.

If you forget to use it

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, then go back to taking it as you would normally.

If you use too much (overdose)

If you take more **CERUVIN** than you should it may lead to longer bleeding time and bleeding complications. Immediately telephone your doctor 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 **CERUVIN**. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using it

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking **CERUVIN**.

- Take **CERUVIN** exactly as your doctor has prescribed, and have any blood tests promptly if your doctor orders them.
- Ask your doctor whether there are any activities you should avoid while taking **CERUVIN**, for example certain sports. Sometimes after an injury bleeding

may occur inside your body without you knowing about it.

- Tell your doctor immediately if you are injured while taking **CERUVIN**. It may take longer than usual to stop bleeding while you are taking **CERUVIN**.

Things you must not do

Do not suddenly stop taking **CERUVIN** without telling your doctor.

Do not give **CERUVIN** to anyone else even if their symptoms seem similar or they have the same condition as you. Your doctor has prescribed **CERUVIN** for you and your condition.

Things to be careful of

Be careful driving or operating machinery until you know how **CERUVIN** affects you. As with other medicines, **CERUVIN** may cause faintness or dizziness in some people. Make sure you know how you react to **CERUVIN** before you drive a car or operate machinery, or do anything else that could be dangerous if you are faint or dizzy. If this occurs, do not drive.

Side Effects

Like other medicines, **CERUVIN** may cause some unwanted 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.

Do not be alarmed by the following list of side effects. You may not experience any of them.

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

Serious side effects

If any of the following happens, stop taking SOBRIUM TABLETS and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- fever and bruising under the skin that may appear as red pinpoint dots, with or without unexplained extreme tiredness, confusion, yellowing of the skin or eyes (thrombotic thrombocytopenic purpura)

- allergic reaction such as rashes, hives, itching, blistering, swelling of deep layers of skin, purple colored itchy rash affecting face, hands, arms, neck, nails, soles, hair or other parts of the body, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing, difficulty in swallowing (hypersensitivity reactions, anaphylactoid reaction, angioedema)
- fever, swollen joints and joint pain, muscle pain, swollen lymph nodes and/or flu-like symptoms (serum sickness)
- irregular red patches on the skin of the hands and arms; serious illness with blistering of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome, toxic epidermal necrolysis); small, purplish raised patches of skin or spots (lichen planus); circular, irregular red patches on the skin of the hands and arms (erythema multiforme)

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

- severe upper stomach pain, often with nausea and vomiting caused by inflammation of the pancreas (pancreatitis)
 - nose bleed (epistaxis); unusual bleeding or bruising under the skin (haematoma); blood in the urine; blood in the eye; blood in vomit or when emptying bowels or black, tarry stools; bleeding inside the head characterised by severe headache, weakness or paralysis of limbs or face, difficulty speaking, sudden loss of consciousness
 - fever, malaise, loss of appetite, diarrhoea, nausea, abdominal discomfort, dark-coloured urine and a yellowing of the skin and whites of the eyes, fatigue, weight loss or weakness, confusion, impaired judgment, or trouble concentrating, stomach/upper abdomen pain, (acute liver failure, fatty liver, infectious hepatitis)
- Other side effects**
- Tell your doctor or pharmacist if you notice any of the following and they worry you:**
- frequent infections such as fever, severe chills, sore throat or mouth ulcers (lack of white blood cells); bleeding or bruising more easily than normal (thrombocytopenia); loss of appetite, tiredness, headache, being short of breath when exercising, dizziness and looking pale (anemia)
 - headache; light headedness (dizziness); tingling sensation of the skin (paraesthesia); decreased feeling or sensitivity, especially in the skin (hypoesthesia); pain situated on the nerve route (neuralgia); sensation of spinning (vertigo); leg cramp
 - fainting; feeling the heart beats
 - an ulcer in the stomach or intestine characterised by stomach pain, nausea, vomiting, indigestion (gastric ulcer and duodenal ulcer); indigestion; feeling sick (nausea); being sick (vomiting); constipation; diarrhoea; abdominal pain
 - rash; hives; itching, purple or red-brown spots visible through your skin (purpura); skin rash, itching, redness and a burning feeling (eczema); skin ulceration
 - chest pain; accidental/inflicted injury; fever or other signs of infection, such as a sore throat runny nose, cough and chills, pain, tiredness; unusual weakness (asthenia); fever; part of an internal organ or tissue bulges through a weak area of muscle (hernia); death and disintegration of a tissue resulting from interference with its blood supply (ischemic necrosis)
 - swelling of arms, hands, feet, ankles or other part of the body (oedema); high blood pressure; cardiac failure characterised by breathlessness, difficulty breathing when lying down, swelling of the feet or legs.
 - irregular heart beat (atrial fibrillation)
 - painful swelling of the joints (gout), back pain, muscle pain, pain or stiffness in the joints
 - feelings of deep sadness and unworthiness; feeling nervous or anxious; difficulty sleeping
 - upper respiratory tract infection (the common cold), including sore throat and nasal congestion; difficulty in breathing; runny or blocked nose; tightness of the chest, wheezing, coughing or difficulty breathing; coughing; fever, chills, shortness of breath, cough, phlegm and occasionally blood (pneumonia); Sinusitis characterised by a feeling of fullness in the nose, cheeks and behind your eyes, blocked or runny nose; anxiety, chest pain, low blood pressure, pale, cool and clammy skin, rapid heart rate, rapid, shallow breathing, restlessness, shortness of breath (hemothorax)
 - uncontrollable, involuntary passing of urine, pain on urination, characterised by burning sensations during urination and frequent, urgent need to urinate (urinary tract infection, cystitis); decreased urine output with puffy eyes (acute renal failure)
 - clouding of the lens of the eye causing blurred vision (cataract); red and swollen eyes
 - confusion, seeing, feeling or hearing things that are not true; taste disorders
 - difficulty breathing, wheezing and tightness in the chest (bronchospasm); swelling of the lungs causing coughing and difficulty breathing (interstitial pneumonitis)
 - high blood pressure, swelling around the feet, ankles, lower legs, and eyes, reduced urination and dark urine (glomerulonephritis)
 - blood vessel inflammation which may result in skin rashes (vasculitis); decrease in blood pressure
 - pain in the gut and diarrhoea caused by inflammation of the bowel (colitis); sore mouth

Effect on laboratory tests

- increase in bleeding time.
- high uric acid levels in the blood
- increase in the amount of non-protein nitrogen (NPN)
- changes in kidney function tests (e.g. blood and creatinine in urine)
- increased liver enzymes
- presence of increased amounts of bilirubin in the blood
- abnormal blood cell counts

Tell your doctor if you notice anything unusual or if you are concerned about any aspect of your health, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.

Date of Revision:

26/05/2015

Serial Number

BPFK(R4/1)220515/00117

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers→ Reporting)

Storage and Disposal of CERUVIN

Storage

Store below 25°C, protected from moisture

Disposal

Return any unused or expired medicine to your doctor, pharmacist or health care professional for safe disposal.

Product Description

What CERUVIN looks like

Pink coloured, round, film-coated tablets with 'C4' debossed on one side and plain on the other side.

Ingredients

Active ingredient:

Each film-coated tablet contains:

Clopidogrel bisulphate

equivalent to Clopidogrel75 mg

Inactive ingredients:

Lactose Monohydrate (Direct Compression Grade) , Microcrystalline Cellulose (AVICEL PH112), Low substituted-Hydroxypropylcellulose (Grade LH21), Macrogol 6000, Hydrogenated Castor Oil (Cutina HR-powder), Opadry Pink 03B54564, Purified Water.

MAL No.

MAL08010791A

Manufacturer and Product Registration Holder

RANBAXY (MALAYSIA) SDN. BHD.

Lot 23, Bakar Arang Industrial Estate,
08000 Sungai Petani, Kedah