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PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S2

TRINPRIN 100 GASTRO-RESISTANT TABLETS
Acetylsalicylic Acid (Aspirin)
Contains sugar - lactose monohydrate

Read all of this leaflet carefully because it contains important information for you
TRINPRIN 100 is available without a doctor's prescription, for you to treat a mild illness / maintain your health. Nevertheless, you still need to take TRINPRIN 100 carefully to get the best results from it.
- Keep this leaflet. You may need to read it again;
- Do not share TRINPRIN 100 with any other person;
- Ask your health care provider or pharmacist if you need more information or advice;
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet
1. What TRINPRIN 100 is and what it is used for
2. What you need to know before you take TRINPRIN 100
3. How to take TRINPRIN 100
4. Possible side effects
5. How to store TRINPRIN 100
6. Contents of the pack and other information

1. What TRINPRIN 100 is and what it is used for

The active ingredient in TRINPRIN 100 is aspirin, also known as acetylsalicylic acid. In adults, TRINPRIN 100 is used to treat the following heart related conditions:
- To reduce the risk of a heart attacks in patients with unstable angina (a condition in which your heart does not get enough blood flow and oxygen) or in patients who have had a previous heart attack.
- To reduce the risk of recurrent strokes (when the blood supply to part of your brain is interrupted or reduced) in patients who have had strokes of the brain due to blood clotting.
- To reduce the risk of blockage of a vascular bypass graft shortly after the bypass is performed.
- For reducing the risk of heart attacks in people with heart risk factors.

2. What you need to know before you take TRINPRIN 100

Do not take TRINPRIN 100:
- If you are hypersensitive (allergic) to aspirin (acetylsalicylic acid), other salicylates or to any of the other ingredients of TRINPRIN 100;
- If you have ever had a bad reaction to aspirin or any other non-steroidal anti-inflammatory medicines (you have ever had asthma, swelling of the lips or face, itchy skin or runny nose after taking them);
- You have a history of stomach ulcers (gastric or duodenal ulcers) or bleeding related to previous use of NSAIDs (medicines against pain, fever or inflammation) including TRINPRIN 100;
- If you have an active ulcer in your stomach or intestine (gastric or duodenal);
- If you have a tendency to bleed or bruise easily (haemorrhagic diathesis);
- If you suffer from severe kidney disease (eGFR < 30 mL/minute);
- If you suffer from severe liver disease (Child-Pugh C);
- If you suffer from severe heart failure diseases (NYHA grade III or IV);
- If you are taking a medicine called methotrexate (e.g., for cancer or rheumatoid arthritis) in doses higher than 15mg per week;
- if you are in your last 3 months of pregnancy.

Warnings and precautions
Take special care with TRINPRIN 100:
- Use TRINPRIN 100 with caution between 20 to 30 weeks of pregnancy and do not use TRINPRIN 100 during the third trimester of your pregnancy (see 'Do not take TRINPRIN 100 ' above). You doctor or specialist will determine whether the use of TRINPRIN 100 is deemed necessary. Do not use TRINPRIN 100 during your pregnancy unless it has been prescribed by your doctor or gynaecologist for a specific reason.
- Use TRINPRIN 100 with caution if you are allergic to pain medications, anti-inflammatory medicines, anti-rheumatism medicines or if you suffer from other allergies.
- Use TRINPRIN 100 with caution if you a history of stomach or intestinal ulcers including chronic or recurrent ulcer disease or a history of gastrointestinal bleedings.
- If you are elderly. The elderly has an increased frequency of adverse reactions to NSAIDs, especially gastrointestinal bleeding and perforation (PUBs) which may be fatal.
- The risk of gastrointestinal bleeding or perforation (PUBs) is higher with increasing doses of TRINPRIN 100, especially in patients with a history of ulcers and the elderly.
- When intestinal bleeding or ulceration occurs while taking TRINPRIN 100, treatment with TRINPRIN 100 should be stopped immediately.
- TRINPRIN 100 should be given with caution to patients with a history of gastrointestinal disease (e.g., ulcerative colitis, Crohn's disease, hiatus hernia, gastro-oesophageal reflux disease, angiodysplasia) as the condition may be exacerbated.
- Use TRINPRIN 100 with caution if you have been diagnosed with kidney or liver problems. If your kidney function or your heart circulation are impaired (e.g., renal vascular disease, congestive heart failure, volume depletion, major surgery, sepsis or major haemorrhagic events), since TRINPRIN 100 may further increase the risk of kidney impairment and acute kidney failure;
- If you take anticoagulants or blood thinning products (medicines to prevent blood clots);
- If you suffer from severe glucose-6-phosphate dehydrogenase (G6PD) deficiency (a human enzyme defect), since TRINPRIN 100 may cause the destruction of red blood cells with release of hemoglobin (hemolysis or hemolytic anemia). Factors that may increase the risk of haemolysis are, for example, high dosage, fever or acute infections;
- TRINPRIN 100 may cause a narrowing and obstruction of the breathing airways and induce asthma attacks and other allergic reactions. Use TRINPRIN 100 with caution if you are asthmatic, have hay fever, nasal polyps or other chronic respiratory diseases; aspirin may induce asthma attack.
- Inform your doctor if you are planning to have an operation (even a minor one, such as tooth extraction) since TRINPRIN 100 have a blood-thinning effect and may increase the risk of bleeding.
- Bleeding may result in an acute or chronic condition in which there is a deficiency of red cells or of haemoglobin in the blood (known as anaemia), resulting in paleness and weariness.
- At low doses, aspirin reduces the excretion of uric acid. This can possibly trigger gout attacks in predisposed patients.
- If you take metamizole or nonsteroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen and naproxen (medication against pain, fever or inflammation) (see Other Medicines and TRINPRIN 100.
- If you develop serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis have been reported. TRINPRIN 100 should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.

Children and adolescents
TRINPRIN 100 should not be used in children and adolescents for viral infections with or without fever without consulting a health care provider. A condition known as Reye's syndrome, a very rare but possibly life-threatening illness may develop, requiring immediate medical action. The risk may be increased when TRINPRIN 100 is given concomitantly. Should persistent vomiting occur, this may be a sign of Reye's syndrome.

Other medicines and TRINPRIN 100
Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)
Please inform your health care provider if you are currently taking any of the following medicines listed below:
- Warfarin or other blood thinners.
- Other non-steroidal anti-inflammatory medicines, like ibuprofen (to relieve pain, reduce swollen joints, muscles and ligaments).
- Methotrexate (used for the treatment of cancer, skin problems, rheumatic problems, Crohn's disease).
- Medicines for depression.
- Digoxin (used for the treatment of heart failure).
- Sulphonamide antibiotics (e.g., Co-trimoxazole).
- Water tablets (diuretics e.g., spironolactone and acetazolamide).
- Corticosteroids like prednisolone (used for many conditions such as pain, swelling, allergy, asthma, rheumatism and skin problems).
- Medicines used to treat high blood pressure like ACE inhibitors (e.g., ramipril, captopril).
- Valproic acid (for epilepsy or fits).
- Probenecid and sulfinpyrazone (for gout).
- Metamizole and some NSAIDs, such as ibuprofen and naproxen may decrease TRINPRIN 100's effectiveness in preventing the sticking together and clumping of blood platelets (thrombocytes) and therefore the prevention of blood clots (thrombi); as a consequence, this may limit TRINPRIN 100 's protection against heart attack and stroke.

TRINPRIN 100 with alcohol
Do not drink alcohol whilst taking TRINPRIN 100. Drinking alcohol may possibly increase the risk of gastrointestinal bleeding and prolong bleeding time.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking TRINPRIN 100.
You should not take TRINPRIN 100 if you are pregnant or breastfeeding your baby unless advised by your doctor or specialist (see 'Do not take TRINPRIN 100 and 'Warnings and precautions' above).

Driving and using machines
It is not always possible to predict to what extent TRINPRIN 100 may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which TRINPRIN 100 affects you. However, due to possible side effect such as dizziness, you should check how you react to TRINPRIN 100 first, before driving a vehicle or operating machinery. If in doubt, talk to your doctor.

TRINPRIN 100 contains lactose monohydrate
TRINPRIN 100 contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor, pharmacist or nurse before taking TRINPRIN 100.

3. How to take TRINPRIN 100

Do not share medicines prescribed for you with any other person.
Always take TRINPRIN 100 exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

The tablets should be swallowed whole. Do not chew, break or crush the tablets as this will destroy the protective effect of the gastro-resistant coating.

Adults
The usual dose is 100 mg daily.

For reducing the risk of heart attacks in people with increased cardiovascular risk: 100 mg to be taken every day preferably at the same time each day according to your individual needs, as determined by your medical practitioner.

Children
TRINPRIN 100 is not recommended for use in paediatric patients, below 18 years.

Patients with liver impairment
TRINPRIN 100 is contraindicated in patients with severe liver failure. TRINPRIN 100 should be used with particular caution in patients with impaired liver function.

Patients with kidney impairment
TRINPRIN 100 should not be used in patients with severe kidney failure. TRINPRIN 100 should be used with particular caution in patients with impaired kidney function since TRINPRIN 100 may further increase the risk of kidney impairment and acute kidney failure.

If you have the impression that the effect of TRINPRIN 100 is too strong or too weak, tell your doctor, pharmacist or nurse.

If you take more TRINPRIN 100 than you should
In the event of overdosage, consult your doctor, pharmacist or nurse. If neither is available, contact the nearest hospital or poison centre. Dizziness and ringing in the ears, particularly in children and elderly patients, may indicate serious poisoning due to overdose. Please contact your doctor if you suspect an overdose of TRINPRIN 100. Your doctor will decide on the necessary measures to be taken depending on the severity of overdose/intoxication.

If you forget to take TRINPRIN 100
If you forget to take a dose, take it as soon as you remember (unless it is nearly time for your next dose, in which case leave out the missed dose). Do not take a double dose to make up for forgotten individual doses.

If you stop taking TRINPRIN 100
Your doctor will decide you how long your treatment with TRINPRIN 100 will last. Do not stop your treatment with TRINPRIN 100 without consulting your doctor first.

4. Possible side effects

TRINPRIN 100 can have side effects.

Not all side effects reported for TRINPRIN 100 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TRINPRIN 100, please inform your health care provider for advice.

If any of the following happens, stop taking TRINPRIN 100 and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Sudden wheezing, swelling of your lips, face or body, rash, fainting, difficulties swallowing (severe allergic reaction) or shock;
- Reddening of the skin with blisters or peeling and may be associated with a high fever and joint pains. This could be symptoms of serious allergic skin reactions;
- Unusual bleeding, such as coughing up blood, blood in your vomit or urine, or a stroke due to bleeding in brain or black stools.

These are all very serious side effects. If you have them, you may have had a serious reaction to TRINPRIN 100. You may need urgent medical attention.

Tell your doctor or health care provider if you notice any of the following:
Frequent:
- Heartburn
- Gastrointestinal and stomach pain
- Stomach inflammation
- Stomach bleeding
- Nosebleed
- Runny nose
- Rash
- Itchy skin
- Blood in the urine
- Ringing in the ears
- Dizziness

Less frequent:
- Bleeding gums
- Stomach ulcer and perforation
- Serious bleedings of the stomach and brain
- Liver enzyme increase
- Liver impairment
- Bruising
- Bleeding
- Nasal congestion
- Muscle bleeding
- Hives
- Kidney impairment
- Acute kidney failure

Frequency unknown
- Intestinal diaphragm disease, a rare but serious complication of nonsteroidal anti-inflammatory drug (NSAID) use in which diaphragm-like strictures develop in the large and/or small intestines
- Increased risk of bleeding during surgery, nose bleeds, blood in the urine, gums, etc.
- Iron deficiency
- Hypersensitivity reactions
- Aspirin Exacerbated Respiratory Disease (AERD), a chronic inflammatory disorder of the sinuses and lungs

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

Reporting of side effects
If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications:
https://www.sahpra.org.za/Publications/Index/8.
By reporting side effects, you can help provide more information on the safety of TRINPRIN 100.

5. How to store TRINPRIN 100

Store all medicines out of sight and reach of children.
Store at or below 30 ºC (room temperature).
Do not take TRINPRIN 100 after the expiry date which is stated on the label or carton. The expiry date refers to the last day of that month.
Return all unused medicines to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What TRINPRIN 100 contains
The active substance is acetylsalicylic acid (aspirin). Each tablet contains 100 mg acetylsalicylic acid (aspirin).
The other ingredients are lactose monohydrate, microcrystalline cellulose, colloidal anhydrous silica, potato starch, talc, triacetin and methacrylic acid-ethylacrylate copolymer (1:1).

What TRINPRIN 100 looks like
TRINPRIN 100 is white coloured gastro-resistant coated tablets, round and biconvex, without break-score packed in PVC/Aluminium blisters containing 10, 20, 28, 30, 50, 56, 60, 90 or 100 gastro-resistant tablets. Not all pack sizes may be marketed.

Holder of Certificate of Registration
Trinity Pharma (Pty) Ltd.
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South Africa
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SKEDULERINGSTATUS S2

TRINPRIN 100 GASTRO-WEERSTANDIGE TABLETTE
Asetielsalisielsuur (Aspirien)
Bevat suiker - laktosemonohidraat

Lees al hierdie pamflet aandagtig deur, want dit bevat belangrike inligting vir jou
TRINPRIN 100 is beskikbaar sonder die voorskrif van 'n dokter om 'n ligte siektetoestand te behandel / jou gesondheid te handhaaf. Nietemin moet jy TRINPRIN 100 noukeurig neem om die beste resultate daaruit te kry.
- Bewaar hierdie pamflet. Dalk moet jy dit weer lees;
- Moenie TRINPRIN 100 met enige ander persoon deel nie;
- Raadpleeg jou gesondheidsorgverskaffer of apteker indien jy meer inligting of advies benodig;
- Jy moet 'n dokter besoek indien jou simptome vererger of nie verbeter nie.

Wat is in hierdie pamflet

1. Wat TRINPRIN 100 is en waarvoor dit gebruik word
2. Wat u moet weet voordat u TRINPRIN 100 neem
3. Hoe om TRINPRIN 100 te neem
4. Moontlike newe-effekte
5. Hoe om TRINPRIN 100 te bewaar
6. Inhoud van die verpakking en ander inligting

1. Wat TRINPRIN 100 is en waarvoor dit gebruik word
Die aktiewe bestanddeel in TRINPRIN 100 is aspirien, ook bekend as asetielsalisielsuur. In volwassenes word TRINPRIN 100 gebruik om die volgende hartverwante toestande te behandel:
- Om die risiko van hartaanvalle te verminder in pasiënte met onstabiele angina ('n toestand waarin u hart nie genoeg bloedvloei en suurstof kry nie) of in pasiënte wat 'n vorige hartaanval gehad het.
- Om die risiko van herhaalde beroertes te verminder (wanneer die bloedtoevoer na 'n deel van jou brein onderbreek of verminder word) in pasiënte wat beroertes van die brein gehad het as gevolg van bloedstolling.
- Om die risiko van blokkasie van 'n vaskulêre omlyning te verminder kort nadat die omlyning uitgevoer is.
- Vir die vermindering van die risiko van hartaanvalle in persone met hartrisikofaktore.

2. Wat jy moet weet voor jy TRINPRIN 100 neem
Moenie TRINPRIN 100 neem:
- Indien jy hipersensitief (allergies) is vir aspirien (asetielsalisielsuur), ander salisilate of enige van die ander bestanddele in TRINPRIN 100;
- Indien jy al ooit 'n slegte reaksie teenoor aspirien of enige ander nie-steroïed anti-inflammatoriese medisyne gehad het (simptome van asma, swelling van die lippe of gesig, jeukerige vel of loopneus nadat jy dit geneem het);
- Jy 'n geskiedenis van maagsere (maag- of duodenale ulkusse) of bloeding wat verband hou met die vorige gebruik van NSAIM's (medisyne teen pyn, koors of inflammasie), insluitend TRINPRIN 100 het;
- Indien jy 'n aktiewe ulkus in jou maag of ingewande het (maag of duodenale);
- Indien jy 'n neiging het om maklik te bloei of te kneus (hemorragiese diatese);
- Indien jy aan ernstige niersiekte ly (eGFT < 30 ml/minuut);
- Indien jy aan ernstige lewersiekte ly (Child-Pugh C);
- Indien jy aan ernstige hartversakingsiektes ly (NYHA graad III of IV);
- Indien jy 'n medisyne genaamd metotreksaat gebruik (byvoorbeeld vir kanker of rumatoïede artritis) in dosisse hoër as 15 mg per week;
- Indien jy in jou laaste 3 maande van swangerskap is.

Waarskuwings en voorsorgmaatreëls
Wees veral versigtig met TRINPRIN 100:
- Gebruik TRINPRIN 100 met omsigtigheid tussen 20 en 30 weke van swangerskap en moenie TRINPRIN 100 gedurende die derde trimester van u swangerskap gebruik nie (sien 'Moenie TRINPRIN 100 hierbo neem nie). U dokter of spesialis sal bepaal of die gebruik van TRINPRIN 100 nodig geag word. Moenie TRINPRIN 100 tydens u swangerskap gebruik nie, tensy dit om 'n spesifieke rede deur u dokter of ginekoloog voorgeskryf is.
- Gebruik TRINPRIN 100 met omsigtigheid in jy allergies is vir pynmedikasie, anti-inflammatoriese medisyne, medisyne teen rumatiek of indien jy aan ander allergieë ly.
- Gebruik TRINPRIN 100 met omsigtigheid indien jy 'n geskiedenis van maag- of dermsere het, insluitend chroniese of herhalende ulkussiekte of 'n geskiedenis van gastro-intestinale bloeding.
- Indien jy bejaard is. Bejaardes het 'n verhoogde kans van nadelige reaksies op NSAID's, veral gastro-intestinale bloeding en perforasie (PUB's) wat dodelik kan wees.
- Die risiko van gastro-intestinale bloeding of perforasie (PUB's) is hoër met toenemende dosisse van TRINPRIN 100, veral in pasiënte met 'n geskiedenis van ulkusse asook in bejaardes.
- Wanneer derm bloeding of ulserasie voorkom tydens die neem van TRINPRIN 100, moet behandeling met TRINPRIN 100 onmiddellik gestaak word.
- TRINPRIN 100 moet met omsigtigheid gegee word aan pasiënte met 'n geskiedenis van gastro-intestinale siektes (bv. ulseratiewe kolitis, Crohn se siekte, mantelvliesbreuk, gastro-oesofageale reflukssiekte, angiodisplasia) aangesien die toestand vererger kan word.
- Gebruik TRINPRIN 100 met omsigtigheid indien jy met nier- of lewerprobleme gediagnoseer is. Indien jou nierfunksie of hartsirkulasie benadeel word (byvoorbeeld vaskulêre siekte van die niere, kongestiewe hartversaking, volume-uitputting, groot chirurgie, sepsis of ernstige hemorragiese voorvalle), aangesien TRINPRIN 100 die risiko van nierinkorting en akute nierversaking verder kan word;
- Indien jy anti-stolmiddels of bloedverdunningsprodukte neem (medisyne om bloedklonte te voorkom);
- Indien jy aan ernstige glukose-6-fosfaatdehidrogenase (G6FD) tekort ly ('n menslike ensiemdefek), aangesien TRINPRIN 100 die vernietiging van rooibloedselle kan veroorsaak met vrystelling van hemoglobien (hemolise of hemolitiese anemie). Faktore wat die risiko van hemolise kan verhoog, is byvoorbeeld hoë dosisse aspirien, koors of akute infeksies;
- TRINPRIN 100 kan 'n vernouing en obstruksie van die asemhalingslugweë veroorsaak en asma-aanvalle en ander allergiese reaksies veroorsaak. Gebruik TRINPRIN 100 met omsigtigheid indien jy asma, hooikoors, neuspoliepe of ander chroniese asemhalingsiektes het; aspirien kan asma-aanvalle veroorsaak.
- Stel jou dokter in kennis indien jy van plan is om 'n operasie te ondergaan (selfs 'n geringe een, soos tandtrek), aangesien TRINPRIN 100 'n bloedverdunningseffek het en die risiko van bloeding kan verhoog.
- Bloeding kan lei tot 'n akute of chroniese toestand waarin daar 'n tekort aan rooibloedselle of haemoglobien in die bloed is (bekend as bloedarmoede), wat lei tot bleekheid en moegheid.
- By lae dosisse verminder aspirien die uitskeiding van uriensuur. Dit kan moontlik jigaanvalle by predisponeerde pasiënte veroorsaak.
- Indien jy metamisool of nie-steroïed anti-inflammatoriese middels (NSAIM's) gebruik, soos ibuprofien en naproksen (medikasie teen pyn, koors of inflammasie) (sien 'Ander medisyne en [PRODUKNAAM').
- Indien jy ernstige velreaksies ontwikkel, sommige kan dodelik wees, insluitend eksfoliatiewe dermatitis, Stevens-Johnson-sindroom en toksiese epidermale nekrolise. TRINPRIN 100 moet gestaak word by die eerste voorkoms van veluitslag, mukosale letsels of enige ander teken van hipersensitiwiteit.

Kinders en adolessente
TRINPRIN 100 moet nie in kinders en adolessente gebruik word vir die behandeling van virale infeksies, met of sonder koors, sonder om 'n gesondheidsorgverskaffer te raadpleeg nie. 'n Toestand bekend as Reye-sindroom, 'n baie seldsame, maar moontlik lewensbedreigende siekte, kan ontwikkel, wat onmiddellike mediese aandag vereis. Die risiko kan verhoog word wanneer TRINPRIN 100 gelyktydig gegee word. Indien aanhoudende braking voorkom, kan dit 'n teken van Reye se sindroom wees.

Ander medisyne en TRINPRIN 100
Lig altyd jou gesondheidsorgverskaffer in indien jy enige ander medisyne gebruik. (Dit sluit alle komplementêre of tradisionele medisyne in.)
Stel asseblief jou gesondheidsorgverskaffer in kennis indien jy tans een van die volgende medisyne gebruik wat hieronder gelys word:
- Warfarien of ander bloedverdunners.
- Ander nie-steroïed anti-inflammatoriese medisyne, soos ibuprofien (om pyn te verlig, geswelde gewrigte, spiere en ligamente te verminder).
- Metotreksaat (gebruik vir die behandeling van kanker, velprobleme, rumatiese probleme, Crohn se siekte).
- Medisyne vir depressie.
- Digoksien (gebruik vir die behandeling van hartversaking).
- Sulfoonamied antibiotika (bv. ko-trimoksasool)
- Watertablette (diuretika bv. spironolaktoon en asetasolamied).
- Kortikosteroïede soos prednisoloon (gebruik vir baie toestande soos pyn, swelling, allergie, asma, rumatiek en velprobleme).
- Medisyne wat gebruik word om hoë bloeddruk te behandel soos AOE-remmers (byvoorbeeld ramipril, kaptopril).
- Valproïensuur (vir voorkoming van epilepsie of epilepsieaanvalle).
- Probenesied en sulfienpirasoon (vir jig).
- Metamisool en sommige NSAIM's, soos ibuprofien en naproksen, kan die effektiwiteit van TRINPRIN 100 verminder om te voorkom dat bloedplaatjies (trombosiete) aanmekaar vassit en saamklont en dus die voorkoming van bloedklonte (trombi); gevolglik kan dit TRINPRIN 100 se beskerming teen hartaanval en beroerte beperk.

TRINPRIN 100 met alkohol
Moenie alkohol gebruik terwyl jy TRINPRIN 100 neem nie. Alkoholverbruik kan moontlik die risiko van gastro-intestinale bloeding verhoog en bloedingstyd verleng.

Swangerskap, borsvoeding en vrugbaarheid
Indien jy swanger is of borsvoed, vermoed dat jy swanger is of van plan is om 'n swanger te raak, raadpleeg jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy TRINPRIN 100 neem.
Jy mag nie TRINPRIN 100 neem indien jy swanger is of jou baba borsvoed nie, tensy jy deur jou dokter of spesialis aangeraai word (sien 'Moenie TRINPRIN 100 neem nie' en 'Waarskuwings en voorsorgmaatreëls' hierbo).

Bestuur en gebruik masjiene
Dit is nie altyd moontlik om te voorspel tot watter mate TRINPRIN 100 jou daaglikse aktiwiteite belemmer kan word nie. Jy moet seker maak dat jy nie aan bogenoemde aktiwiteite deelneem nie voordat jy bewus tot watter mate TRINPRIN 100 jou beïnvloed. As gevolg van moontlike newe-effekte soos duiseligheid, moet jy egter eers kyk hoe jy op TRINPRIN 100 reageer voordat jy 'n voertuig bestuur of masjinerie gebruik. Indien jy twyfel, raadpleeg met jou dokter.

TRINPRIN 100 bevat laktosemonohidraat
TRINPRIN 100 bevat laktosemonohidraat. Indien jy deur jou dokter meegedeel is dat jy 'n onverdraagsaamheid teenoor sommige suikers het, kontak jou dokter,

3. Hoe om TRINPRIN 100 te neem
Moenie medisyne wat vir jou voorgeskryf is, met enige ander persoon deel nie.
Neem altyd TRINPRIN 100 presies soos beskryf word in hierdie pamflet of soos jou dokter, apteker of verpleegster jou instruksie gegee het. Raadpleeg jou dokter, apteker of verpleegster indien jy onseker is.

Die tablette moet heel ingesluk word. Moenie die tablette kou, breek of fynmaak nie, want dit sal die beskermende effek van die gastro-weerstandige laag vernietig.

Volwassenes
Die normale dosis is 100 mg per dag.

Vir die vermindering van die risiko van miokardiale iskemiese gebeurtenisse in mense met verhoogde kardiovaskulêre risiko:
100 mg moet elke dag, verkieslik op dieselfde tyd elke dag geneem word volgens die individuele behoeftes van die pasiënt, soos bepaal deur die mediese praktisyn.

Kinders
TRINPRIN 100 word nie aanbeveel vir gebruik in pediatriese pasiënte onder 18 jaar nie.

Pasiënte met lewerinkorting
TRINPRIN 100 is teenaangedui in pasiënte met ernstige lewerversaking. TRINPRIN 100 moet met besondere omsigtigheid gebruik word in pasiënte met verswakte lewerfunksie.

Pasiënte met nierinkorting
TRINPRIN 100 moet nie gebruik word in pasiënte met ernstige nierversaking nie. TRINPRIN 100 moet met besondere omsigtigheid gebruik word in pasiënte met nierversaking, aangesien TRINPRIN 100 die risiko van nierinkorting en akute nierversaking verder kan verhoog.

Indien jy die indruk kry dat die effek van TRINPRIN 100 te sterk of te swak is, raadpleeg jou dokter, apteker of verpleegster.

Indien jy meer TRINPRIN 100 neem as wat jy moet
In die geval van oordosering, raadpleeg jou dokter, apteker of verpleegster. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum. Duiseligheid en suising in die ore, veral in kinders en bejaarde pasiënte, kan op ernstige vergiftiging aandui as gevolg van oordosering. Kontak asseblief jou dokter indien jy oordosering van TRINPRIN 100 vermoed. Jou dokter sal besluit oor die nodige maatreëls wat getref moet word, afhangende van die erns van oordosering / vergiftiging.

Indien jy vergeet om TRINPRIN 100 te neem
Indien jy vergeet om 'n dosis te neem, neem dit sodra jy onthou (tensy dit amper tyd is vir jou volgende dosis, in welke geval, moet die dosis nie geneem word). Moenie 'n dubbeldosis neem om op te maak vir 'n vergete individuele dosis nie.

Indien jy ophou om TRINPRIN 100 te neem
Jou dokter sal besluit hoe lank jou behandeling met TRINPRIN 100 sal duur. Moenie jou behandeling met TRINPRIN 100 staak sonder om eers jou dokter te raadpleeg nie.

4. Moontlike newe-effekte
TRINPRIN 100 kan newe-effekte hê.

Nie alle newe-effekte wat vir TRINPRIN 100 gerapporteer word, is in hierdie pamflet ingesluit nie. Indien jou algemene gesondheid vererger of indien jy enige newe-effekte ervaar terwyl jy TRINPRIN 100 neem, stel asseblief jou gesondheidsorgverskaffer in kennis vir advies.

Indien een van die volgende voorkom, hou op om TRINPRIN 100 te neem en raadpleeg jou dokter onmiddellik of gaan na die ongevalle-afdeling by jou naaste hospitaal:
- Skielike asemnood, swelling van jou lippe, gesig of liggaam, uitslag, floute, probleme om te sluk (ernstige allergiese reaksie) of skok;
- Rooiheid van die vel met blase of afskilfering geassosieer met 'n hoë koors en gewrigspyne. Dit kan simptome van ernstige allergiese velreaksies wees;
- Ongewone bloeding, soos ophoes van bloed, bloed in jou braaksel of urine, of 'n beroerte as gevolg van bloeding in die brein of swart stoelgang.

Hierdie is alles baie ernstige newe-effekte. Indien jy dit ervaar, het jy moontlik 'n ernstige reaksie teenoor TRINPRIN 100 gehad. Jy het dringende mediese hulp nodig.

Raadpleeg jou dokter of gesondheidsorgverskaffer indien jy enige van die volgende opmerk:
Gereeld:
- Sooibrand
- Gastro-intestinale pyn en maagpyn
- Maagontsteking
- Maagbloeding
- Neusbloeding
- Loopneus
- Uitslag
- Jeukerige vel
- Bloed in die urine
- Suising in die ore
- Duiseligheid

Minder gereeld:
- Bloeding van tandvleis
- Maagseer en perforasie
- Ernstige bloeding van die maag en brein
- Lewerensiemtelling verhoog
- Lewerinkorting
- Kneusplekke
- Bloeding
- Neuskongestie
- Spierbloeding
- Veluitslag met korwe
- Nierinkorting
- Akute nierversaking

Frekwensie onbekend
- Intestinale diafragma-siekte, 'n seldsame maar ernstige komplikasie van nie-steroïed anti-inflammatoriese middel (NSAIM) waarin diafragma-agtige beperkings in die groot en / of dunderm ontwikkel
- Verhoogde risiko van bloeding tydens operasie, neusbloeding, bloed in die urine, tandvleis, ens.
- Ystertekort
- Hipersensitiwiteitsreaksies
- Aspirien verergerende respiratoriese siekte (AVRS), 'n chroniese inflammatoriese afwyking van die sinusse en longe

Indien jy enige newe-effekte opmerk wat nie in hierdie pamflet genoem word nie, moet jy asseblief jou dokter, apteker of verpleegster in kennis stel.

Rapportering van newe-effekte
Indien jy newe-effekte ervaar, raadpleeg jou dokter of apteker. Jy kan ook newe-effekte aan SAHPRA rapporteer via die "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8.
Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van TRINPRIN 100 te verskaf.

5. Hoe om TRINPRIN 100 te bewaar
Bewaar alle medisyne buite sig en bereik van kinders.
Stoor by of benede 30 °C (kamertemperatuur).
Moenie TRINPRIN 100 neem na die vervaldatum wat op die etiket of karton aangedui word nie. Die vervaldatum verwys na die laaste dag van daardie maand.
Stuur alle ongebruikte medisyne terug aan jou apteker.
Moenie ongebruikte medisyne in dreine of rioolstelsels (byvoorbeeld toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting
Wat TRINPRIN 100 bevat
Die aktiewe bestanddeel is asetielsalisielsuur (aspirien). Elke tablet bevat 100 mg asetielsalisielsuur (aspirien).
Die ander bestanddele is laktosemonohidraat, mikrokristallyn sellulose, kolloïdale anhidriese silika, aartappelstysel, talk, triasien en metakrielsuur-etielakrilaat-kopolimeer (1:1).

Hoe TRINPRIN 100 lyk
TRINPRIN 100 is witkleurige gastro-weerstandige, bedekte tablette, wat rond en bikonveks is, sonder 'n breeklyn, verpak in PVC / aluminium stulpverpakking wat 10, 20, 28, 30, 50, 56, 60, 90 of 100 gastro-weerstandige tablette bevat. Nie alle pakgroottes mag moontlik bemark word nie.

Houer van Registrasiesertifikaat
Trinity Pharma (Edms) Bpk.
3 Gwen Laan, Vierde Vloer,
Sandton, Gauteng
Suid-Afrika
2031

Hierdie pamflet is laas hersien in
06 Februarie 2024

Registrasie / Aansoeknommer
TRINPRIN 100: 53/8/0370.368

Toegang tot die ooreenstemmende Professionele inligting:
www.trinitypharma.co.za

2401A003

11.2024/1053/ZA

GI70321ZA, Trinprin 100 mg Fta.

Präparatenamen/Stärke:
Trinprin 100 mg
Darreichungsform:
Filmabletten
Abpackungsart:
Blister

Art.-Nr.: GI70321ZA
Code-Nr.: 11.2024/1053/ZA
Land: Südafrika / za
Format: 148 x 420 mm
Packmittelart: Gebrauchsinformation
Produktion: intern
Schrift: Helvetica narrow Punkt
Druckfarbe: ◆Schwarz
Version: 1
Datum: 12.03.2024
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