

Patient Information Leaflet

TRIZINE Tablets

Sulphadiazine 410mg/Trimethoprim 90mg

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What Trizine Tablets is used for

Trizine is used to treat infections caused by susceptible micro-organisms including upper and lower respiratory tract infections; renal, urinary, genital and gastrointestinal tracts infections; skin infections.

How Trizine Tablets works

TRIZINE is a type of antibacterial medicine, which works by killing bacteria.

Before you use Trizine Tablets

- When you must not take it
 - Are allergic (hypersensitive) to trimethoprim, sulphonamides or any of the other ingredients
 - have severe liver damage or jaundice
 - have any blood disorder or porphyria (a genetic disease)
 - have severe kidney disease
 - are pregnant or planning to become pregnant or breast feeding

- Before you start to take it

WARNINGS:

Fatalities associated with the administration of sulphonamides and trimethoprim, either alone or in combination, have occurred due to severe reactions, include Stevens-Johnson syndrome, toxic epidermal necrolysis and other reactions. The drug should be

discontinued at the first appearance of skin rash or any sign of adverse reaction.

Check with your doctor or pharmacist before taking TRIZINE tablets if you:

- have a history of severe allergic reactions or bronchial asthma
- have reduced amount of the enzyme glucose 6 phosphate dehydrogenase (G6PD). You may react badly when you eat certain types of foods such as fava beans
- have a protein disorder called phenylketonuria
- have Group A beta-haemolytic streptococci (a bacterial infection)
- have malnutrition
- are elderly (as you may suffer with more side effects).

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Especially:

- ACE inhibitors (to treat high blood pressure e.g. captopril, lisinopril)
- amantidine (to treat parkinsonism or some viral infections)
- anaesthetics such as prilocaine
- antiarrhythmics such as procainamide, amiodorone, dofetilide (to treat some heart conditions)
- antibiotics such as rifampicin, dapsone, methenamine
- anticoagulants to prevent your blood clotting such as warfarin
- antivirals such as lamivudine, zidovudine, zalcitabine
- ascorbic acid
- ciclosporin (to prevent rejection after transplantation)
- clozapine (to treat mental health problems)
- cytotoxic drugs such as methotrexate, azathioprine,

mercaptopurine (to treat some cancers, severe psoriasis or severe rheumatoid arthritis)

- digoxin (to treat heart conditions)
- diuretics ('water tablets') such as bendroflumethiazide
- phenytoin (to treat epilepsy)
- pyrimethamine (to treat malaria)
- potassium aminobenzoate (to treat scleroderma, Peyronie's disease)
- sulphonylureas (to treat diabetes)

How to take Trizine Tablets

- How much to take

Adults and children over 12 years: 1 tablet twice a day

Children:

3 months-5 years: ¼ tablet twice a day

6-12 years: ½ tablet twice a day

- When to take it

Always take the tablets exactly as your doctor has told you to. The dose will be on the pharmacist's label. Check the label carefully. It should tell you how many tablets to take, and how often. If you are not sure, ask your doctor or pharmacist.

- How long to take it

Keep taking the tablets for as long as you have been told unless you have any problems. In that case, check with your doctor.

- If you forget to take it

If you forget to take a dose, take it as soon as you remember it and then take the next dose at the right time. Do not take a double dose to make up for a forgotten dose. Do not stop taking TRIZINE tablets because you feel better. Take the tablets for as long as your doctor has told you or your problem may come back.

- If you take too much (overdose)

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your

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nearest hospital casualty department or tell your doctor immediately. Signs of an overdose include dizziness, feeling or being sick, rash, headache, unsteady movements, drowsiness, difficulty urinating, swelling of the face, weakness and confusion.

While you are using Trizine Tablets

- Things you must do

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

- Things you must not do

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

- Things to be careful of

Driving and using machines:
TRIZINE tablets may make you feel drowsy or dizzy or cause hallucinations, ringing in the ears or sleeplessness. Make sure you are not affected before you drive or operate machinery.

Blood tests:

If you see another doctor or go into hospital, let them know you are taking TRIZINE, as it can affect the results of some blood tests. If you are having treatment over a long time, your doctor may carry out regular blood counts.

Side Effects

Like all medicines, TRIZINE tablets can cause side-effects, although not everybody gets them. Stop taking the tablets and contact a doctor at once if you get a skin rash, or severe allergic reaction such as swelling of the face, lips, tongue or throat, difficulty breathing, fever, inflamed heart or blood vessels (chest pain, fever, a fast

heartbeat, tiredness), systemic lupus erythematosus (SLE-skin rash, hair loss, difficulty breathing and joint pains), Stevens-Johnson syndrome (severe skin rash with flushing, fever, blisters or ulcers) or toxic epidermal necrolysis (severe rash involving reddening, peeling and swelling of the skin that resembles severe burns).

Aseptic meningitis can occur in some patients as a combination of symptoms such as headache, fever, stiff neck, tiredness, feeling ill and sensitivity of eyes to bright light.

Tell your doctor if you notice any of the following side-effects or notice any other effects not listed:

Blood: altered number and type of certain blood cells. If you get increased bruising, nose bleeds, sore throats or infections, consult your doctor.

Nervous system: headaches, depression, dizziness, hallucinations, fits, lack of co-ordination, numbness of fingers or toes, drowsiness, fatigue, sleeplessness.

Stomach: feeling or being sick, diarrhoea, loss of appetite, pseudomembranous colitis (causing severe and painful diarrhoea).

Liver: jaundice (yellowing of the skin or whites of the eyes), changes in liver function, liver damage (fatigue, weakness, loss of appetite, weight loss, abdominal pain, fever) or inflammation of the pancreas (pancreatitis – abdominal pain just below the ribs, being sick, fever and generally feeling unwell).

Other: sore throat or mouth, cough, inflamed skin, sensitivity to light, disorder with blood spots, bruising and discolouration to the skin, joint inflammation and stomach pain (Henoch-Schonlein purpura), 'spinning' sensation, ringing in the ears, muscle or joint pain, fungal infections, kidney problems and crystal in the urine (this can be avoided by drinking plenty of water), changes in levels of body chemicals especially sodium and potassium.

Storage and Disposal of Trizine Tablets

Storage

Store below 30°C in a dry place. Protect from light.

Disposal

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

Take any unused tablets back to your pharmacist to be destroyed. Only keep the tablets if the doctor tells you to. Do not throw them away with your normal household water or waste. This will help to protect the environment.

Product Description

- What it looks like

White, round and normal convex tablets, 12mm diameter with cross score-line and without logo.

- Ingredients

Active Ingredient

Sulphadiazine 410mg/tablet
Trimethoprim 90mg/tablet

Inactive ingredients

Corn starch, Povidone 30,
Sodium starch glycolate,
Magnesium stearate

- MAL No.

MAL 19900590A

Manufacturer

Drug Houses of Australia Pte. Ltd.,

#09-01/02 Haw Par Tiger Balm Building
No.2 Chia Ping Road, Singapore 619968.

Marketing Authorization Holder

Ascent Pharmahealth Malaysia Sdn Bhd

Unit 304, Level 3, Uptown 2, 2
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Date of Revision

09-2011

RiMUP

TRIZINE Tablet

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Apakah yang ada pada risalah ini

- Apakah kegunaan Trizine Tablet
- Bagaimana Trizine Tablet berfungsi
- Sebelum mengambil Trizine Tablet
- Cara menggunakan Trizine Tablet
- Semasa menggunakan Trizine Tablet
- Kesan-kesan sampingan
- Cara penyimpanan dan pelupusan Trizine Tablet
- Maklumat lanjut
- Pengilang
- Pemegang Pendaftaran Produk
- Tarikh kemaskini RiMUP

Apakah kegunaan Trizine Tablet

Trizine Tablet digunakan untuk merawat jangkitan yang disebabkan oleh mikroorganisma berpengaruh termasuk jangkitan salur pernafasan atas dan bawah; salur kencing, kemaluan dan salur gastro usus; jangkitan kulit.

Bagaimana Trizine Tablet berfungsi

Trizine adalah sejenis ubat antibakteria yang berfungsi untuk membunuh bakteria.

Sebelum mengambil Trizine Tablet

- Bila tidak boleh mengambil
 - alergi (hipersensitif) kepada trimethoprim, sulphonamides atau mana-mana ramuan yang lain.
 - Mengalami masalah hati yang serius atau jaundis.
 - Mengalami masalah dengan darah atau porphyria (sejenis penyakit genetik).
 - Jika anda hamil, ingin mengandung atau sedang menyusui.

- Sebelum mula mengambil AMARAN:
Kematian yang berkaitan dengan pengambilan sulphonamides dan trimethoprim, secara individu atau kombinasi, pernah terjadi disebabkan oleh reaksi serius, termasuk sindrom Stevens-Johnson, nekrosis toksik epidermis dan reaksi lain. Ubat ini perlu dihentikan pada penampilan pertama ruam kulit atau mana-mana tanda tindak balas yang buruk.

Periksa dengan doktor atau ahli farmasi anda sebelum anda mengambil ubat TRIZINE Tablet jika anda:

- Mempunyai sejarah reaksi alergi yang teruk atau asma bronkial
- Mempunyai kandungan enzim glukosa 6 fosfat dehidrogenase (G6PD) yang rendah. Anda kemungkinan mengalami reaksi teruk jika anda makan beberapa jenis makanan seperti kacang Fava.
- Mengalami masalah protein yang dipanggil phenylketonuria
- Mempunyai Jenis A streptococci beta hemolitik (sejenis jangkitan bacteria)
- Mengalami malnutrisi
- Adalah orang tua (kerana anda mungkin menderita dengan kesan sampingan yang lebih).

- Jika mengambil ubat-ubat lain

Sila beritahu doktor atau ahli farmasi anda jika anda mengambil atau baru-baru pernah mengambil sebarang ubat-ubatan, termasuk ubat-ubat tanpa preskripsi. Terutamanya:

- ACE inhibitors (untuk merawat tekanan darah tinggi e.g. captopril, lisinopril)
- amantidine (untuk merawat penyakit

Parkinson atau sejenis jangkitan virus)

- anestetik seperti prilocaine
- antiarrhythmics seperti procainamide, amiodorone, dofetilide (untuk merawat masalah jantung)
- antibiotik seperti rifampicin, dapsone, methenamine
- anticoagulants untuk mengelakkan pembekuan darah seperti warfarin
- antivirals seperti lamivudine, zidovudine, zalcitabine
- asid askorbik
- ciclosporin (untuk mengelakkan penolakan selepas prosedur pemindahan)
- clozapine (untuk merawat masalah mental)
- ubat sitotoksik seperti methotrexate, azathioprine, mercaptopurine (untuk merawat beberapa jenis kanser, psoriasis yang teruk atau arthiritis reumatoid yang teruk)
- digoxin (untuk merawat masalah jantung)
- ubat diuretik seperti bendroflumethiazide
- phenytoin (untuk merawat epilepsi)
- pyrimethamine (untuk merawat malaria)
- potassium aminobenzoate (untuk merawat scleroderma, penyakit Peyronie)
- sulphonylureas (untuk merawat kencing manis)

Cara menggunakan Trizine Tablet

- Berapa banyak harus diambil
Dewasa dan kanak-kanak lebih daripada 12 tahun:
1 tablet dua kali sehari

Kanak-kanak:
3 bulan-5 tahun:
¼ tablet dua kali sehari
6-12 tahun:
½ tablet dua kali sehari.

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- Bila perlu diambil
Selalu ambil ubat seperti yang diarahkan oleh doktor anda. Label pada pek tersebut akan memberitahu anda apa dos anda perlu mengambil dan berapa kerap mengambil. Jika ada masih tidak pasti, tanya doktor atau ahli farmasi anda.

- Berapa lama perlu diambil
Sentiasa ambil ubat anda seberapa lama yang anda telah diberitahu kecuali anda mengalami sebarang masalah. Untuk kes ini, periksa dengan doktor anda.

- Jika terlupa mengambil
Jika anda terlupa mengambil satu dos, ambil dos tersebut sebaik saja anda mengingatnya dan ambil dos seterusnya pada masa yang ditetapkan. Jangan ambil dos berganda untuk mengganti dos yang telah dilupa. Jangan berhenti mengambil ubat TRIZINE Tablet oleh kerana anda rasa lebih baik.

- Jika mengambil berlebihan (terlebih dos)
Jika anda (atau orang lain) mengambil berlebihan dos, atau anda mengesyaki kanak-kanak telah terlebih ambil tablet, hubungi hospital berhampiran atau beritahu doktor anda dengan segera. Simptom-simptom terlebih dos termasuk pening, rasa tidak selesa, ruam, sakit kepala, pergerakan yang tidak mantap, rasa mengantuk, susah untuk buang air kecil, muka kembang, lemah dan kekeliruan.

Semasa menggunakan Trizine Tablet

- Perkara yang perlu dilakukan
Adalah mustahak untuk anda menyimpan senarai ubat-ubat preskripsi dan bukan preskripsi yang anda sedang mengambil, termasuk vitamin, mineral atau ubat supplemen yang lain. Anda patut bawa senarai ini dengan anda setiap kali anda

jumpa doktor anda atau jika anda masuk hospital. Ia juga merupai maklumat penting untuk dibawa bersama anda jika berlaku kecemasan.

- Perkara yang tidak boleh dilakukan
Jangan bagi ubat anda kepada orang lain. Sila tanya ahli farmasi anda jika anda mempunyai sebarang pertanyaan mengenai pengisian semula ubat.

- Perkara yang perlu diberi perhatian
Memandu dan mengendalikan mesin:
TRIZINE Tablet mungkin menyebabkan anda rasa mengantuk atau pening atau menyebabkan halusinasi, bunyi dering di dalam telinga atau tidur. Pastikan anda tidak mengalaminya sebelum memandu atau mengendalikan mesin.

Ujian darah:

Jika anda berjumpa dengan doktor lain atau pergi ke hospital, beritahu mereka bahawa anda sedang mengambil TRIZINE Tablet, kerana ia boleh mempengaruhi keputusan beberapa ujian darah. Jika anda menjalani rawatan untuk masa yang panjang, doktor anda mungkin perlu menjalankan pengiraan darah yang tetap.

Kesan-kesan sampingan

Seperti semua ubat, TRIZINE boleh menyebabkan kesan sampingan, walaupun tidak semua orang mengalaminya. Berhenti mengambil ubat dan hubungi doktor dengan segera jika anda mengalami ruam kulit, atau reaksi alergi yang teruk seperti bengkak muka, bibir, lidah atau tekak, kesusahan bernafas, demam, radang jantung atau saluran darah (sakit dada, demam, degupan jantung yang cepat, letih), systemic lupus erythematosus (SLE-ruam kulit, keguguran rambut, sesak nafas dan sakit sendi), Stevens-Johnson syndrome (teruk ruam

kulit dengan curahan, demam, ulser atau lepuh) atau necrolysis toksik epidermis (ruam yang teruk yang melibatkan kemerahan, mengelupas dan bengkak kulit yang nampak seperti kebakaran yang teruk. Meningitis aseptik boleh berlaku pada sesetengah pesakit sebagai satu kombinasi gejala seperti demam sakit kepala, leher kaku, keletihan, sakit dan kepekaan mata terhadap cahaya yang terang. Beritahu doktor anda jika anda melihat apa-apa kesan sampingan yang berikut atau apa-apa notis kesan lain yang tidak disenaraikan:

Darah: Bilangan berubah dan jenis sel darah tertentu. Jika anda mendapat meningkat lebam, berdarah hidung, sakit tekak atau jangkitan, berjumpa dengan doktor.

Sistem saraf: sakit kepala, kemurungan, pening, halusinasi, sawan, kurang penyelarasan, kebas jari atau jari kaki, mengantuk, keletihan, tidur.

Perut: perasaan atau sedang sakit, cirit-birit, hilang selera makan, kolitis pseudomembranous (menyebabkan cirit-birit teruk dan menyakitkan).

Hati: jaundis (kuning pada kulit atau putih mata), perubahan dalam fungsi hati, kerosakan hati (keletihan, lemah, hilang selera makan, kehilangan berat badan, sakit perut, demam) atau radang pankreas (pankreatitis - sakit perut hanya di bawah tulang rusuk, sakit, demam dan secara amnya merasa tidak sihat).

Lain-lain: sakit tekak atau mulut, batuk, radang kulit, sensitif kepada cahaya, gangguan dengan tompok darah, lebam dan perubahan warna pada kulit, keradangan sendi dan sakit perut (Henoch-Schonlein Purpura), 'berputar' sensasi, nada di telinga, otot atau sakit sendi, jangkitan kulat, masalah buah pinggang dan

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kristal dalam air kencing (ini dapat dielakkan dengan minum air yang banyak), perubahan dalam paras bahan kimia badan terutamanya natrium dan kalium.

Cara penyimpanan dan pelupusan Trizine Tablet

Penyimpanan

Simpan di bawah suhu 25°C dan di tempat yang kering. Lindungi dari cahaya.

Pelupusan

Jangan makan ubat itu apabila telah lepas tarikh luputnya.

Pulang tablet yang belum digunakan kepada ahli farmasi anda untuk dilupuskan. Hanya simpan tablet jika doktor anda menasihatkannya. Jangan buang ubat tersebut di dalam air atau bersama-sama dengan sampah-sarap rumah. Tindakan ini boleh membantu melindungi alam persekitaran.

Maklumat lanjut

- Rupa dan warna produk
Berwarna putih, berbentuk bulat dan biasa, 12mm diameter dengan palang garis-skor tanpa logo.

- Bahan-bahan kandungan
Ramuan aktif
Sulphadiazine 410mg/tablet
Trimethoprim 90mg/tablet

Bahan-bahan tidak aktif
Corn starch, Povidone 30,
Sodium starch glycolate,
Magnesium stearate

- Nombor MAL
MAL 19900590A

Pengilang

Drug Houses of Australia Pte. Ltd.,
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Pemegang Pendaftaran Produk

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Tarikh kemaskini RiMUP

09-2011