For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

CLOTAN

1. Generic Name
Tolfenamic Acid Capsules 200 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each hard gelatin capsule contains:
Tolfenamic acid B.P…….200mg
(Sodium Methyl paraben I.P. used as preservative)
Approved colours used in hard gelatin capsule shells.

The excipients used are Starch, Lactose, Polyethylene glycol 6000, Povidone, Talc, Hard gelatin capsule Maroon/Yellow.

3. DOSAGE FORM AND STRENGTH
Hard Gelatin Capsule, 200 mg

4. CLINICAL PARTICULARS
4.1 Therapeutic Indication
Rheumatoid arthritis, osteo arthritis, ankylosing spondylitis and related conditions associated with pain. Additional indication of migraine.

4.2 Posology and Method of Administration
Posology

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see 4.4 Special warnings and precautions for use).

ADULTS

Migraine - acute attacks:

200mg when the first symptoms of migraine appear. The treatment can be repeated once after 1-2 hours if a satisfactory response is not obtained.

CHILDREN

A paediatric dosage regimen has not yet been established.

ELDERLY

The elderly is at increased risk of the serious consequences of adverse reactions. If an NSAID is considered necessary, the lowest effective dose should be used and for the shortest possible duration. The patient should be monitored regularly for GI bleeding during NSAID therapy.

Method of administration

For oral administration.

To be taken preferably with or after food.

4.3 Contraindications

- Hypersensitivity to Tolfenamic acid or to any of the excipients.
- Active, or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding).
- NSAIDs are contraindicated in patients who have previously shown hypersensitivity reactions (e.g. asthma, rhinitis, angioedema or urticaria) in response to ibuprofen, aspirin, or other non-steroidal anti-inflammatory drugs.
- Severe heart failure, hepatic failure and renal failure.
- During the last trimester of pregnancy.
- History of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy.

4.4 Special Warnings and Precautions for Use

In all patients:

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms.

The use of Tolfenamic acid with concomitant NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided.

Elderly:

The elderly has an increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation which may be fatal.

Respiratory disorders:

Caution is required if administered to patients suffering from, or with a previous history of, bronchial asthma since NSAIDs have been reported to precipitate bronchospasm in such patients.

Cardiovascular, renal and hepatic impairment:

The administration of an NSAID may cause a dose dependent reduction in prostaglandin formation and precipitate renal failure.

Patients at greatest risk of this reaction are those with impaired renal function, cardiac impairment, liver dysfunction, those taking diuretics and the elderly. Renal function should be monitored in these patients.

Cardiovascular and cerebrovascular effects:

Appropriate monitoring and advice are required for patients with a history o f hypertension and/or mild to moderate congestive heart failure as fluid retention and oedema have been reported in association with NSAID therapy.

Clinical trial and epidemiological data suggest that use of some NSAIDs (particularly at high doses and in long term treatment) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke). There are insufficient data to exclude such a risk for Tolfenamic acid.

Patients with uncontrolled hypertension, congestive heart failure, established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease should only be treated with Tolfenamic acid after careful consideration. Similar consideration should be made before initiating longer-term treatment of patients with risk factors for

cardiovascular disease (e.g. hypertension, hyperlipidaemia, diabetes mellitus, and smoking).

Gastrointestinal bleeding, ulceration and perforation:

GI bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs at any time during treatment, with or without warning symptoms or a previous history of serious GI events.

The risk of GI bleeding, ulceration or perforation is higher with increasing NSAID doses, in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation, and in the elderly. These patients should commence treatment on the lowest dose available. Combination therapy with protective agents (e.g. misoprostol or proton pump inhibitors) should be considered for these patients, and also for patients requiring concomitant low dose aspirin, or other drugs likely to increase gastrointestinal risk.

Patients with a history of GI toxicity, particularly when elderly, should report any unusual abdominal symptoms (especially GI bleeding) particularly in the initial stages of treatment.

Caution should be advised in patients receiving concomitant medications which could increase the risk of ulceration or bleeding, such as oral corticosteroids, anticoagulants such as warfarin, selective serotonin-reuptake inhibitors or anti-platelet agents such as aspirin.

When GI bleeding or ulceration occurs in patients receiving Tolfenamic acid, the treatment should be withdrawn.

NSAIDs should be given with care to patients with a history of gastrointestinal disease (ulcerative colitis, Crohn's disease) as these conditions may be exacerbated.

SLE and mixed connective tissue disease:
In patients with systemic lupus erythematosus (SLE) and mixed connective tissue disorders there may be an increased risk of aseptic meningitis.

Dermatological:
Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis, have been reported very rarely in association with the use of NSAIDs. Patients appear to be at highest risk for these reactions early in the course of therapy: the onset of the reaction occurring in the majority of cases within the first month of treatment. Tolfenamic acid should be discontinued at the first appearance of skin rash, mucosal lesions or any other sign of hypersensitivity.

Impaired female fertility:
The use of Tolfenamic acid may impair female fertility and is not recommended in women attempting to conceive. In women who have difficulties conceiving or who are undergoing investigation of infertility, withdrawal of Tolfenamic acid should be considered.

Preclinical Safety Data
The therapeutic index for Tolfenamic acid is high, and gastrointestinal ulceration and kidney changes have only been seen with oral doses approximately 6-10 times the maximum therapeutic dose recommended for Tolfenamic acid. In human volunteers, Tolfenamic acid did not affect renal function.

4.5 Drugs Interactions

Other analgesics including cyclooxygenase-2 selective inhibitors: Avoid concomitant use of two or more NSAIDs (including aspirin) as this may increase the risk of adverse effects.

Anti-hypertensives:
Reduced anti-hypertensive effect.

Diuretics:
Reduced diuretic effect. Diuretics can increase the risk of nephrotoxicity of NSAIDs.

Cardiac glycosides:
NSAIDs may exacerbate cardiac failure, reduce GFR and increase plasma glycoside levels.

Lithium:
The effect of lithium may be increased due to decreased elimination of lithium.

Methotrexate:
Decreased elimination of methotrexate.
Ciclosporin:
Increased risk of nephrotoxicity.

Mifepristone:
NSAIDs should not be used for 8-12 days after mifepristone administration as NSAIDs can reduce the effect of mifepristone.

Corticosteroids:
Increased risk of gastrointestinal ulceration or bleeding.

Anti-coagulants:
NSAIDs may enhance the effects of anti-coagulants, such as warfarin. In patients treated with anti-coagulants, close monitoring of blood coagulation is recommended.

Quinolone antibiotics:
Animal data indicate that NSAIDs can increase the risk of convulsions associated with quinolone antibiotics. Patients taking NSAIDs and quinolones may have an increased risk of developing convulsions.

Anti-platelet agents and selective serotonin reuptake inhibitors (SSRIs):

Increased risk of gastrointestinal bleeding.

Tacrolimus:
Possible increased risk of nephrotoxicity when NSAIDs are given with tacrolimus.

Zidovudine:
Increased risk of haematological toxicity when NSAIDs are given with zidovudine. There is evidence of an increased risk of haemarthrosis and haematoma in HIV (+) haemophiliacs receiving concurrent treatment with zidovudine and ibuprofen.

4.6 Use in Special Populations (Such as Pregnant Women, Lactating Women, Paediatric Patients, Geriatric Patients Etc.)
Pregnancy:

Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/foetal development. Data from epidemiological studies suggest an increased risk of miscarriage and of cardiac malformation and gastroschisis after use of a prostaglandin synthesis inhibitor in early pregnancy. The absolute risk for cardiovascular malformation was increased from less than 1%, up to approximately 1.5%. The risk is believed to increase with dose and duration of therapy. In animals, administration of a prostaglandin synthesis inhibitor has been shown to result in increased pre- and post-implantation loss and embryo-foetal lethality. In addition, increased incidences of various malformations, including cardiovascular, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenetic period. During the first and second trimester of pregnancy, tolfenamic acid should not be given unless clearly necessary. If tolfenamic acid is used by a woman attempting to conceive, or during the first and second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible.

During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the foetus to:

- cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension)

- renal dysfunction, which may progress to renal failure with oligo-hydroamniosis

the mother and the neonate, at the end of the pregnancy, to:

- possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses

- inhibition of uterine contractions resulting in delayed or prolonged labour.

Consequently, tolfenamic acid is contraindicated during the third trimester of pregnancy.

Lactation:

In limited studies so far available, NSAIDs can appear in breast milk in very low concentrations. NSAIDs should, if possible, be avoided when breastfeeding.

4.7 Effects On Ability to Drive and Use Machines
Undesirable effects such as dizziness, drowsiness, fatigue and visual disturbances are possible after taking NSAIDs. If affected, patients should not drive or operate machinery.

4.8 Undesirable Effects
Tolfenamic acid is well tolerated at the recommended dosage.

The following side effects have been observed:

Gastrointestinal:

The most commonly-observed adverse events are gastrointestinal in nature. Peptic ulcers, perforation or GI bleeding, sometimes fatal, particularly in the elderly, may occur (see 4.4 Special warnings and precautions for use). Nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease (see 4.4 Special warnings and precautions for use) have been reported following administration. Less frequently, gastritis has been observed. Pancreatitis has been reported very rarely.

Hypersensitivity:

Hypersensitivity reactions have been reported following treatment with NSAIDs. These may consist of (a) non-specific allergic reactions and anaphylaxis (b) respiratory tract reactivity comprising asthma, aggravated asthma, bronchospasm or dyspnoea, or (c) assorted skin disorders, including rashes of various types, pruritus, urticaria, purpura, angioedema and, more rarely exfoliative and bullous dermatoses (including epidermal necrolysis and erythema multiforme).

Cardiovascular and cerebrovascular:

Oedema, hypertension and cardiac failure have been reported in association with NSAID treatment.

Clinical trial and epidemiological data suggest that use of some NSAIDs (particularly at high doses and in long term treatment) may be associated with an increased risk of arterial thrombotic events (for example myocardial infarction or stroke) (see 4.4 Special warnings and precautions for use).

Other adverse reactions reported less commonly include:

Renal:

Nephrotoxicity in various forms, including interstitial nephritis, nephrotic syndrome and renal failure. Harmless dysuria in the form of smarting during urination may occur occasionally, most commonly in males. The occurrence is correlated with the concentration of a metabolite and is most probably due to a local irritating effect of the urethra. Increased consumption of liquid or reduction of the dose diminishes the risk of smarting. The urine may, due to coloured metabolites, become a little more lemon coloured.

Hepatic:

Abnormal liver function, hepatitis and jaundice.

Neurological and special senses:

Visual disturbances, optic neuritis, headaches, paraesthesia, reports of aseptic meningitis (especially in patients with existing auto-immune disorders, such as systemic lupus erythematosus, mixed connective tissue disease), with symptoms such as stiff neck, headache, nausea, vomiting, fever or disorientation (see 4.4 Special warnings and precautions for use), depression, confusion, hallucinations, tinnitus, vertigo, tremor, euphoria, dizziness, malaise, fatigue and drowsiness.

Haematological:

Thrombocytopenia, neutropenia, agranulocytosis, aplastic anaemia and haemolytic anaemia.

Dermatological:

Bullous reactions including Stevens Johnson Syndrome and Toxic Epidermal Necrolysis (very rare). Photosensitivity.

4.9 Overdose

Symptoms

Symptoms include headache, nausea, vomiting, epigastric pain, gastrointestinal bleeding, rarely diarrhoea, disorientation, excitation, coma, drowsiness, dizziness, tinnitus, fainting, occasionally convulsions. In cases of significant poisoning acute renal failure and liver damage are possible.

Therapeutic measure

Patients should be treated symptomatically as required. Within one hour of ingestion of a potentially toxic amount, activated charcoal should be considered. Alternatively, in adults, gastric lavage should be considered within one hour of ingestion of a potentially life-threatening overdose. Good urine output should be ensured. Renal and liver function should be closely monitored. Patients should be observed for at least four hours after ingestion of potentially toxic amounts. Frequent or prolonged convulsions should be treated with intravenous diazepam. Other measures may be indicated by the patient's clinical condition.

5. PHARMACOLOGICAL PROPERTIES

5.1 Mechanism of Action

Tolfenamic acid is a prostaglandin synthesis inhibitor and a leukotriene synthesis inhibitor.

5.2 Pharmacodynamic Properties

Pharmacotherapeutic group: Anti-inflammatory and ant rheumatic products, ATC code: M01AG02.

NSAID with anti-inflammatory, analgesic, and antipyretic effects.

5.3 Pharmacokinetic Properties

Tolfenamic acid is absorbed quickly and almost completely after oral administration.
Hepatic first pass metabolism is as low as 15% (bioavailability 85%). Maximum plasma concentrations are reached after about 1-1½ hours. The half-life in plasma is about 2 hours.
Tolfenamic acid is extensively bound to plasma proteins (99%). It is metabolised in the liver and tolfenamic acid as well as the metabolites is conjugated with glucuronic acid. About 90% of a given dose of tolfena-mic acid is excreted in the urine as glucuronic acid conjugates, and about 10% is excreted in the faeces.
Enterohepatic circulation exists.

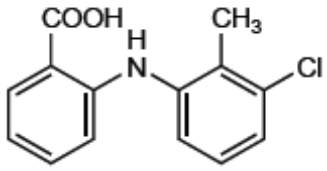
6. NONCLINICAL PROPERTIES

6.1 Animal Toxicology or Pharmacology

The therapeutic index for tolfenamic acid is high, and gastrointestinal ulceration and kidney changes have only been seen with oral doses approximately 6-10 times the maximum therapeutic dose recommended for tolfenamic acid. In human volunteers, tolfenamic acid did not affect renal function.

7. DESCRIPTION

Chemically it is *N*-(3-Chloro-*o*-tolyl) anthranilic acid, empirical formula is $C_{14}H_{12}ClNO_2$ and molecular weight is 261.7. Its structure is:



Product Description:
Tolfenamic capsule is Maroon/Yellow coloured, size '2' hard gelatin capsules printed "Torrent logo" (square emblem only) on body containing white powder. The excipients used are Starch, Lactose, Polyethylene glycol 6000, Povidone, Talc, Hard gelatin capsule Maroon/Yellow

8. PHARMACEUTICAL PARTICULARS

8.1 Incompatibilities

None known.

8.2 Shelf-life

Do not use later than date of expiry.

8.3 Packaging information

Clotan is available in Blister pack of 10 Capsules

8.4 Storage and Handing Instructions

Store in a cool, dry place. Protect from light. Keep out of reach of children.

9. PATIENT COUNSELLING INFORMATION

Package leaflet: Information for the user
Tolfenamic Acid 200mg Capsules
(Tolfenamic Acid)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Tolfenamic Acid 200mg Capsules is and what it is used for

Tolfenamic acid is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs reduce pain.
Tolfenamic Acid 200mg Capsules are effective in treating the pain associated with an acute attack of migraine in adults.

2. What you need to know before you take Tolfenamic Acid 200mg Capsules

Do not take Tolfenamic Acid 200mg Capsules if you
• are allergic to tolfenamic acid or any of the other ingredients
• have previously experienced allergic reactions (e.g. asthma, nasal discharge, nettle rash or swelling of the face, lips, tongue or throat) when taking ibuprofen, aspirin or other NSAIDs
• have severe liver, kidney or heart failure
• are in your last three months of pregnancy
• have or have a history of recurrent peptic ulcer or peptic bleeding (ulcer or bleeding in your stomach or duodenum)
• have ever had bleeding or perforation in your digestive tract due to NSAID treatment

Warnings and precautions
Talk to your doctor or pharmacist before taking Tolfenamic Acid 200mg Capsules.

Take special care with Tolfenamic Acid 200mg Capsules if you
• are taking other NSAIDs including NSAIDs known as COX-2 inhibitors
• are elderly
• have or have had asthma
• have decreased heart, liver or kidney function
• have or have had high blood pressure
• have had a gastrointestinal disease (Crohn's disease or inflammation of the colon and rectum)
• have a connective tissue disease such as systemic lupus erythematosus (SLE)
• have cardiovascular disease, peripheral arterial disease and/or cerebrovascular disease
• have had a peptic ulcer, intestional bleeding or perforation

Medicines such as Tolfenamic Acid 200mg Capsules may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.
If you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes, raised cholesterol, raised triglycerides or are a smoker) you should discuss your treatment with your doctor or pharmacist.

Children
Use in children is not recommended

Other medicines and Tolfenamic Acid 200mg Capsules
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.
- Any other NSAIDs (including aspirin), as Tolfenamic Acid 200mg Capsules may increase the risk of undesirable effects
- Cardiac glycosides (heart medicines), as Tolfenamic Acid 200mg Capsules may increase the risk of undesirable effects and aggravate heart failure
- Corticosteroids (used to treat various inflammatory conditions), as Tolfenamic Acid 200mg Capsules may increase the risk of gastrointestinal undesirable effects
- Quinolones (antibiotics), as Tolfenamic Acid 200mg Capsules may increase the risk of developing convulsions
- Tacrolimus, ciclosporin (medicines used to suppress the immune system), as Tolfenamic Acid 200mg Capsules may increase the risk of kidney problems
- Water Capsules (diuretic medicine), as Tolfenamic Acid 200mg Capsules may increase the risk of kidney problems
- Medicines used to treat anxiety and depression known as selective serotonin re-uptake inhibitors (SSRIs)
- Medicines used to treat high blood pressure
- Mifepristone (abortion pill)
- Lithium (used to treat certain mental conditions)
- Methotrexate (used to treat e.g. cancer, psoriasis and rheumatism)
- Blood thinners such as warfarin or aspirin
- Zidovudine (used in cases of HIV infection)

Tolfenamic Acid 200mg Capsules with food, drink and alcohol
Tolfenamic Acid 200mg Capsules should be taken with or after food. Drink a glass of water with your medicine.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Abnormalities have been reported in babies whose mothers have taken NSAIDs during pregnancy. During the first and second trimester of pregnancy, tolfenamic acid should not be given unless clearly necessary. You should not take tolfenamic acid during the last three months of pregnancy as it may affect the baby's kidney function and circulation, clotting of the blood in both the mother and baby, and labour.
Tolfenamic Acid should be avoided if you are breast-feeding, as small amounts of the medicine may pass into the breast milk.
Tolfenamic Acid 200mg Capsules may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Driving and using machines
Tolfenamic Acid 200mg Capsules may cause dizziness, drowsiness, exhaustion and visual disturbances. If you are affected by these, do not drive or use machines.

3. How to take Tolfenamic Acid 200mg Capsules
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Your doctor will prescribe a dose suitable for you. Depending on your response the dose may be repeated **once** after 1-2 hours.
The Capsule should be taken orally (by mouth).
The Capsule should be swallowed whole. Drink a glass of water with your medicine.
The usual dose is:
Adults:
Migraine – acute attacks: 200mg when the first symptoms of migraine appear. The treatment can be repeated once after 1-2 hours if a satisfactory effect is not obtained.

Use in children:
Use in children is not recommended.

Elderly:
Your doctor will prescribe a suitable dose for you.

If you take more Tolfenamic Acid 200mg Capsules than you should
If you have taken more Tolfenamic Acid 200mg Capsules than you should, contact your doctor or your local hospital immediately.

If you forget to take Tolfenamic Acid 200mg Capsules
Do not take a double dose to make up for a forgotten dose.

If you stop taking Tolfenamic Acid 200mg Capsules
It is very important that you take your medicine as your doctor has told you to. You should not suddenly stop taking Tolfenamic Acid 200mg Capsules, before you have spoken to your doctor about it.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.
If you suffer from any of the following side effects at any time during your treatment **STOP TAKING** the medicine and **seek immediate medical help:**
• Pass blood in your faeces (stools/motions)
• Pass black tarry stools
• Vomit any blood or dark particles that look like coffee grounds

STOP TAKING the medicine and tell your doctor if you experience:
• Indigestion or heartburn
• Stomach pain or other abnormal stomach symptoms

If any of the following serious side effects occur, **STOP TAKING** this medicine and contact your doctor immediately or go straight to the emergency department at your nearest hospital.
• Peptic ulcer (belching, discomfort in the stomach, vomiting)

• Gastrointestinal bleeding
• An allergic shock reaction shortness of breath, rash or wheezing) (
• Swelling of the face, lips, tongue or throat
• Serious skin reactions with bullous/blister rash, inflammation of the skin and/or the top layer of the skin peels off e.g. Stevens Johnson Syndrome and Toxic Epidermal Necrolysis (very rare)
• Lack of a type of white blood cells (flu-like symptoms, cold, high fever, sore throat)
• Decrease in the number of all blood cells (flu-like symptoms, fatigue, dizziness, spontaneous bleedings)
• Meningitis (stiff neck, headache, fever, nausea, vomiting or disorientation)
• Reddish or purplish spots on the skin
• Hallucinations
• Inflammation of the liver (yellowing of the skin or whites of the eyes)
• Inflammation of the kidney and kidney failure (urination disturbances)
• Bloody stool
• Vomiting of blood
• Allergic reactions such as asthma, aggravated asthma, wheezing, difficulty breathing
• Inflammation of the pancreas (pancreatitis)
• High blood pressure (hypertension)
• Cardiac failure

Other side effects include the following and you should inform your doctor as soon as you notice any of these:
• Swelling
• Nausea
• Vomiting
• Diarrhoea
• Flatulence (wind)
• Constipation
• Indigestion
• Stomach pain
• Inflammation of the mouth or stomach
• Worsening of gastrointestinal diseases (Crohn's disease or inflammation of the colon and rectum)
• Rash
• Itching
• Nettle rash
• Visual disturbances
• Pain in the eye and/or loss of vision
• Headache
• Sensation of pins and needles on the skin
• Depression
• Confusion
• Tinnitus
• Trembling or shaking
• Feeling of elation
• Dizziness
• Vague feeling of weakness
• Exhaustion
• Drowsiness

• Slight pain when passing urine
• Discolouration of urine (little more lemon coloured)
• Decreased liver or kidney function
• Sensitivity to light

Medicines such as Tolfenamic Acid 200mg Capsules may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

5. How to store Tolfenamic Acid 200mg Capsules
Store in a cool, dry place. Protect from light. Keep out of reach of children.

6. Contents of the pack and other information
What Tolfenamic Acid 200mg Capsules contains
- The active substance is tolfenamic acid.
the excipients used are Starch, Lactose, Polyethylene glycol 6000, Povidone, Talc, Hard gelatin capsule Maroon/Yellow.

What Tolfenamic Acid 200mg Capsule look like and contents of the pack
Tolfenamic capsule is Maroon/Yellow coloured, size '2' hard gelatin capsules printed "Torrent logo" (square emblem only) on body containing white powder.

10. DETAILS OF MANUFACTURER
Manufactured By:
Pure and Cure Healthcare Pvt Ltd
Plot No. 26A-30, Sector – 8A, IIE, SIDCUL,
Ranipur, Haridwar – 249403 (Uttarakhand)

11. DETAILS OF PERMISSION OR LICENCE NUMBER WITH DATE
Mfg Lic No.: 31/UA/2013 issued on 28.08.2014.

12. DATE OF REVISION
23/05/2019

MARKETED BY
TORRENT PHARMACEUTICALS LTD.
Torrent House, Off Ashram Road,
Ahmedabad-380 009, INDIA

IN/ CLOTAN 200 mg /May-19/02/PI