OBSAGREL Tablet

اوبساگریل ٹیبلیٹ

(Clopidogrel Bisulphate + Aspirin)

COMPOSITION

Each film coated tablet contains:

Clopidogrel Bisulphate equivalent to
75mg of Clopidogrel.
Aspirin, enteric coated ....75mg.

DESCRIPTION

Clopidogrel:
Clopidogrel bisulphate is an inhibitor of ADP-induced platelet aggregation acting by direct inhibition of adenosine diphosphate (ADP) binding to its receptor and of the subsequent ADP-mediated activation of the glycoprotein GPIIb/IIIa complex.

Aspirin:
Aspirin (acetylsalicylic acid) an analgesic, antipyretic, and anti-inflammatory agent has demonstrated antiinflammatory, analgesic, antipyretic, and antirheumatic activity. Aspirin's mode of action as an antiinflammatory and antirheumatic agent may be due to inhibition of synthesis and release of prostaglandins.

CLINICAL PHARMACOLOGY

Mechanism of Action
Clopidogrel is an inhibitor of platelet aggregation. It inhibits platelet function, by decreasing morbid events with established cardiovascular atherosclerotic disease as evidenced by stroke or transient ischemic attacks, myocardial infarction, unstable angina or the need for vascular bypass or angioplasty.

Aspirin appears to produce analgesia by virtue of both a peripheral and CNS effect. Peripherally, aspirin acts by inhibiting the synthesis and release of prostaglandins. Acting centrally, it would appear to produce analgesia at a hypothalamic site in the brain, although the mode of action is not known.

Clopidogrel selectively inhibits the binding of adenosine diphosphate (ADP) to its platelet receptor and the subsequent ADP-mediated activation of the glycoprotein GPIIb/IIIa complex, thereby inhibiting platelet aggregation.
Dose dependent inhibition of platelet aggregation can be seen 2 hours after single oral doses of OBSAGREL. Repeated doses of 75 mg OBSAGREL per day inhibit ADP-induced platelet aggregation on the first day, and inhibition reaches steady state between Day 3 and Day 7. At steady state, the average inhibition level observed with a dose of 75 mg OBSAGREL per day was between 40% and 60%. Platelet aggregation and bleeding time gradually return to baseline values after treatment is discontinued, generally in about 5 days.

INDICATIONS AND USAGE

OBSAGREL is indicated for the reduction of thrombotic events as follows:

Recent MI, Recent Stroke, or Established Peripheral Arterial Disease
For patients with a history of recent myocardial infarction (MI), recent stroke, or established peripheral arterial disease, OBSAGREL has been shown to reduce the rate of a combined end point of new ischemic stroke (fatal or not), new MI (fatal or not), and other vascular death.

Acute Coronary Syndrome
For patients with acute coronary syndrome (unstable angina/non–Q-wave MI), including patients who are to be managed medically and those who are to be managed with percutaneous coronary intervention (with or without stent) or has been shown to decrease the rate of a combined end point of cardiovascular death, MI, or stroke as well as the rate of a combined end point of cardiovascular death, MI, stroke, or refractory ischemia.

CONTRAINDICATIONS

The use of OBSAGREL is contraindicated in the following conditions:
Hypersensitivity to the drug substance or any component of the product. Active pathological bleeding such as peptic ulcer or intracranial hemorrhage.

WARNINGS

Thrombotic thrombocytopenic purpura (TTP): TTP has been reported rarely following use of OBSAGREL, sometimes after a short exposure (< 2 weeks). TTP is a serious condition requiring prompt treatment. It is characterized by thrombocytopenia, microangiopathic hemolytic anemia, neurological findings, renal dysfunction and fever.

PRECAUTIONS

General

OBSAGREL prolongs the bleeding time and therefore should be used with caution in patients who may be at risk of increased bleeding from trauma, surgery, or other pathological conditions (particularly gastrointestinal and intraocular). If a patient is to undergo elective surgery and an antiplatelet effect is not desired, OBSAGREL should be discontinued 5 days prior to surgery.

Due to the risk of bleeding and undesirable hematological effects, blood cell count determination and/or other appropriate testing should be promptly considered, whenever such suspected clinical symptoms arise during the course of treatment.

Use in Hepatically Impaired Patients: Experience is limited in patients with severe hepatic disease, who may have bleeding diatheses. OBSAGREL should be used with caution in this population.

Use in Renally Impaired Patients: Experience is limited in patients with severe renal impairment. OBSAGREL should be used with caution in this population.

DRUG INTERACTIONS

Study of specific drug interactions yielded the following results:

Aspirin: Clopidogrel potentiated the effect of aspirin on collagen-induced platelet aggregation. Clopidogrel & aspirin have been administered together for up to one year.

Heparin: OBSAGREL did not necessitate modification of the heparin dose or alter the effect of heparin on coagulation. Coadministration of heparin had no effect on inhibition of platelet aggregation induced by OBSAGREL.

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs): Concomitant administration of OBSAGREL was associated with increased occult gastrointestinal blood loss. NSAIDs and OBSAGREL should be coadministered with caution.

Warfarin: Because of the increased risk of bleeding, the concomitant administration of warfarin with OBSAGREL should be undertaken with caution.

Other Concomitant Therapy: No clinically significant pharmacodynamic interactions were observed when OBSAGREL was coadministered with atenolol, nifedipine, or both atenolol and nifedipine. The pharmacodynamic activity of OBSAGREL was also not significantly influenced by the coadministration of phenobarbital, cimetidine or estrogen.

Pregnancy
OBSAGREL should be used during pregnancy only if clearly needed.

Nursing Mothers
Decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the nursing woman.

Pediatric Use
Safety and effectiveness in the pediatric population have not been established.

ADVERSE REACTIONS

OBSAGREL has been evaluated for safety in more than 17,500 patients, including over 9,000 patients treated for 1 year or more. The clinically important adverse events observed are discussed below:

Body as a whole: Allergic reaction, necrosis
Cardiovascular disorders: Edema generalized.
Gastrointestinal system disorders: Gastric ulcer perforated, gastritis hemorrhagic, upper GI ulcer hemorrhagic.
Liver and Biliary system disorders: Bilirubinemia, hepatitis infectious, fatty liver
Platelet, bleeding and clotting disorders: hemarthrosis, hematuria, hemoptysis, hemorrhage intracranial, hemorrhage retroperitoneal, hemorrhage of operative wound, ocular hemorrhage, pulmonary hemorrhage, purpura allergic, thrombocytopenia.
Red blood cell disorders: Anemia aplastic, anemia hypochromic.
Reproductive disorders, female: Menorrhagia.
Respiratory system disorders: Hemothorax.
Skin and appendage disorders: Bullous eruption, rash erythematous, rash maculopapular, urticaria.
Urinary system disorders: Abnormal renal function, acute renal failure.
White cell and reticuloendothelial system disorders: Agranulocytosis, granulocytopenia, leukemia, leukopenia, neutrophils decreased.

Aspirin:
Doses of 1,000 mg per day of aspirin caused gastrointestinal symptoms and bleeding that, in some cases, were clinically significant. The percentage of incidences of gastrointestinal symptoms for aspirin respectively, were stomach pain (14.5%), heartburn (11.9%), nausea and/or vomiting (7.6%), hospitalization for GI disorder (4.9%).

OVERDOSAGE

Platelet transfusion may be appropriate to reverse the pharmacological effects of OBSAGREL if quick reversal is required. Overdosage of 200 to 500 mg/kg is in the fatal range. Early symptoms are CNS stimulation with vomiting, hyperpnea, hyperactivity, and possibly convulsions. This progresses quickly to depression, coma, respiratory failure, and collapse. These symptoms are accompanied by severe electrolyte disturbances. In the treatment of salicylate overdosage, intensive supportive therapy should be instituted immediately.

DOSAGE AND ADMINISTRATION

The recommended daily dose of OBSAGREL is 75 mg once daily.
For patients with acute coronary syndrome (unstable angina/non–Q-wave MI), OBSAGREL should be initiated with a single 300 mg loading dose and then continued at 75 mg once daily. OBSAGREL can be administered with or without food.

PRESENTATION

OBSAGREL Tablets are available in the blister pack of 1 x 10's.

INSTRUCTIONS

To be sold on the prescription of a registered medical practitioner only.
Avoid exposure to heat and light.
Store below 30°C.
Keep out of the reach of children.

خوراک:
ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات: صرف مستند ڈاکٹر کے نسخے پر فروخت کریں۔
دوا کو دھوپ اور گرمی سے بچائیں۔
۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
بچوں کی پہنچ سے دور رکھیں۔

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