Brand Name : AGOSPIRIN-500 TABLETS **Generic Name :** Aspirin Tablets BP 500 mg	2021
Module 1 Administrative Information and Product Information **1.5** Product Information	**Confidential**

1.5 PRODUCT INFORMATION

1.5.1 Prescribing information (Summary of products characteristics)

SUMMARY PRODUCT CHARACTERISTICS

1. Name of drug product:

AGOSPIRIN-500 TABLETS (Aspirin Tablets BP 500 mg)

2. Qualitative and Quantitative Composition:

Each uncoated tablet contains: Aspirin BP 500 mg

3. Pharmaceutical form:

White, circular, flat uncoated tablets having breakline on one side and other side. is plain of each tablet.

.

4. Clinical particulars:

4.1 Therapeutic Indications:

Aspirin, also known as **acetylsalicylic acid** (**ASA**), is a medication used to reduce pain, fever, or inflammation. Specific inflammatory conditions which aspirin is used to treat include Kawasaki disease, pericarditis, and rheumatic fever.

Aspirin given shortly after a heart attack decreases the risk of death. Aspirin is also used long-term to help prevent further heart attacks, ischaemic strokes, and blood clots in people at high risk. For pain or fever, effects typically begin within 30 minutes. Aspirin is a nonsteroidal anti-inflammatory drug (NSAID) and works similarly to other NSAIDs but also suppresses the normal functioning of platelets.

There is evidence that has shown that aspirin as a chemoprotective agent may reduce overall cancer incidence and mortality in colorectal, esophageal and gastric cancers with smaller effects on prostate, breast and lung cancer. A review of randomised control trials showed that doses between 75 and 300 mg daily reduced overall cancer incidence by 12% after 3 years and also demonstrated a 33% reduction in mortality and 25% reduction in the incidence of colorectal cancer with a median follow up of 18.3 years.

Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gauraipada, Vasai (E), Dist. Thane - 401 208. INDIA.
Tel. : 95250 - 2455801 / 2452714 / 2453525 • Fax : 95250 - 2452074 (0091 - 250 - 2452074) • Email : agog@vsnl.net & agogpharma@rediffmail.com

One common adverse effect is an upset stomach. More significant side effects include stomach ulcers, stomach bleeding, and worsening asthma. Bleeding risk is greater among those who are older, drink alcohol, take other NSAIDs, or are on other blood thinners. Aspirin is not recommended in the last part of pregnancy. It is not generally recommended in children with infections because of the risk of Reye syndrome. High doses may result in ringing in the ears.

A precursor to aspirin found in leaves from the willow tree (genus *Salix*) has been used for its health effects for at least 2,400 years. In 1853, chemist Charles Frédéric Gerhardt treated the medicine sodium salicylate with acetyl chloride to produce acetylsalicylic acid for the first time. For the next 50 years, other chemists established the chemical structure and devised more efficient production methods.

4.2 Posology and Method of Administration:

Tablet

- 81 mg
- 325 mg
- 500 mg

Tablet, delayed-release

- 162mg
- 325mg
- 500mg

Tablet, chewable

- 75 mg
- 81 mg

Tablet, enteric-coated

- 81 mg
- 162 mg
- 325 mg
- 650 mg

Gum, chewing, oral

- 227 mg

Extended-release capsule (Durlaza [Rx]) (adult only)

- 162.5 mg

Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gauraipada, Vasai (E), Dist. Thane - 401 208. INDIA.
Tel. : 95250 - 2455801 / 2452714 / 2453525 • Fax : 95250 - 2452074 (0091 - 250 - 2452074) • Email : agog@vsnl.net & agogpharma@rediffmail.com

Dosage Considerations – Should be Given as Follows:

PAIN AND FEVER

Adults: 325-650 mg orally/rectally once every 4-6 hours as needed

Controlled/extended/delayed-release products (enteric-coated): 650-1300 mg orally once every 8 hours; not to exceed 3.9 g/day

Children under 12 years:

- 10-15 mg/kg orally once every 4 hours, up to 60-80 mg/kg/day

Children 12 years and older:

- 325-650 mg orally/rectally once every 4-6 hours as needed
- Controlled/extended/delayed-release products (enteric coated): 650-1300 mg orally once every 8 hours; not to exceed 3.9 g/day

ACUTE CORONARY SYNDROME

For use as adjunctive antithrombotic effects for ACS (ST-segment elevation myocardial infarction [STEMI], unstable angina [UA]/non-ST-segment elevation myocardial infarction [NSTEMI])

Acute symptoms

- 160-325 mg orally; chew non-enteric-coated tablet upon presentation (within minutes of symptoms)
- If unable to take orally, may give 300-600 mg rectal suppository

Maintenance (secondary prevention)

- 75-81 mg orally once/day indefinitely (preferred dose); may give 81-325 mg/day
- Regimen may depend on co-administered drugs or comorbid conditions
- Co-administered with ticagrelor: 81 mg orally once/day

Percutaneous transluminal coronary angioplasty

- Adjunctive aspirin therapy to support reperfusion with primary PCI (with or without fibrinolytic therapy)
- Preoperative dose: 162-325 mg orally before procedure
- Maintenance: 81 mg orally once/day indefinitely (preferred dose) may give 81-325 mg/day
- Regimen may depend on co-administered drugs or comorbid conditions
- Co-administered with ticagrelor: 81 mg orally once/day

Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gauraipada, Vasai (E), Dist. Thane - 401 208. INDIA.
Tel. : 95250 - 2455801 / 2452714 / 2453525 • Fax : 95250 - 2452074 (0091 - 250 - 2452074) • Email : agog@vsnl.net & agogpharma@rediffmail.com

PRIMARY AND SECONDARY PREVENTION

Durlaza: Indicated to reduce the risk of death and heart attack (myocardial infarction/MI) in patients with chronic CAD (e.g., history of MI, unstable angina, or chronic stable angina); also indicated to reduce the risk of death and recurrent stroke in patients who have had an ischemic stroke or transient ischemic attack (TIA)

Extended-release capsule (Durlaza [Rx]): 162.5 mg orally once/day

Use immediate-release aspirin, not extended release capsule in situations where a rapid onset of action of action is required (such as acute treatment of myocardial infarction or before percutaneous coronary intervention)

ISCHEMIC STROKE AND TRANSIENT ISCHEMIC ATTACK

50-325 mg/day orally within 48 hours of stroke or TIA, then 75-100 mg/day orally

OSTEOARTHRITIS

Up to 3 g/day orally in divided doses

RHEUMATOID ARTHRITIS

3 g/day orally in divided doses; increased as needed for anti-inflammatory efficacy (target plasma salicylate, 150-300 mcg/mL)

JUVENILE RHEUMATOID ARTHRITIS

Children less than 25 kg: 60-100 mg/kg/day orally divided every 6-8 hours (maintain serum salicylate at 150-300 mcg/mL)

Children 25 kg or more: 2.4-3.6 g/day

SPONDYLOARTHROPATHY

3.6-5.4 g/day orally in divided doses; monitor serum concentrations

KAWASAKI DISEASE (PEDIATRIC)

Febrile phase: 80-100 mg/kg/day orally divided every 6 hours for up to 14 days (48-72 hours after fever abates)

Maintenance: 3-6 mg/kg/day orally in single dose

Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gauraipada, Vasai (E), Dist. Thane - 401 208. INDIA.
Tel. : 95250 - 2455801 / 2452714 / 2453525 • Fax : 95250 - 2452074 (0091 - 250 - 2452074) • Email : agog@vsnl.net & agogpharma@rediffmail.com

COLORECTAL CANCER (OFF-LABEL)

Prophylaxis

600 mg/day orally

Decreases risk of developing hereditary colorectal cancer (i.e., Lynch syndrome) by 60% if taken daily for at least 2 years

DOSING MODIFICATIONS

Renal impairment

- CrCl greater than 10 mL/min: Dose adjustment not necessary
- CrCl less than 10 mL/min: Not recommended

Hepatic impairment

- Severe liver disease: Not recommended

DOSING CONSIDERATIONS, PEDIATRIC

Toxic dose: 200 mg/kg

WHAT ARE SIDE EFFECTS ASSOCIATED WITH USING ASPIRIN?

Side effects of aspirin include:

- Skin swelling
- Bronchospasm
- Central nervous system (CNS) alteration
- Skin problems
- Gastrointestinal (GI) pain, ulceration, bleeding
- Liver damage
- Hearing loss
- Nausea
- Platelet aggregation inhibition
- Premature hemolysis
- Pulmonary edema (salicylate-induced, non-cardiogenic)
- Rash
- Kidney damage
- Ringing in the ears (tinnitus)
- Hives
- Vomiting

Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gauraipada, Vasai (E), Dist. Thane - 401 208. INDIA.
Tel. : 95250 - 2455801 / 2452714 / 2453525 • Fax : 95250 - 2452074 (0091 - 250 - 2452074) • Email : agog@vsnl.net & agogpharma@rediffmail.com

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Method of administration : Oral.

4.3 Contraindications:

Hypersensitivity to aspirin or nonsteroidal anti-inflammatory drugs (NSAIDs); aspirin-associated hypersensitivity reactions include aspirin-induced urticaria (HLA-DRB1*1302-DQB1*0609 haplotype), aspirin-intolerant asthma (HLA-DPB1*0301)

Allergy to tartrazine dye

Absolute

- Bleeding GI ulcers, hemolytic anemia from pyruvate kinase (PK) and glucose-6-phosphate dehydrogenase (G6PD) deficiency, hemophilia, hemorrhagic diathesis, hemorrhoids, lactating mother, nasal polyps associated with asthma, sarcoidosis, thrombocytopenia, ulcerative colitis

Relative

- Appendicitis, asthma (bronchial), chronic diarrhea, bowel outlet obstruction (for enteric-coated formulations), dehydration, erosive gastritis, hypoparathyroidism

Effects of Drug Abuse

None.

Short-Term Effects

See "What Are Side Effects Associated with Using Aspirin?"

Long-Term Effects

See "What Are Side Effects Associated with Using Aspirin?"

Cautions

Anemia, GI malabsorption, history of peptic ulcers, gout, hepatic disease, hypochlorhydria, hypoprothrombinemia, renal impairment, thyrotoxicosis, vitamin K deficiency, renal calculi, ethanol use (may increase bleeding).

Discontinue therapy if tinnitus develops.

Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gauraipada, Vasai (E), Dist. Thane - 401 208. INDIA.
Tel. : 95250 - 2455801 / 2452714 / 2453525 • Fax : 95250 - 2452074 (0091 - 250 - 2452074) • Email : agog@vsnl.net & agogpharma@rediffmail.com

Should be taken with food or 8-12 oz of water to avoid GI effects.

Not indicated for children with viral illness; use of salicylates in pediatric patients with varicella or influenza-like illness is associated with increased incidence of Reye syndrome.

Heart Failure (HF) risk:

- NSAIDs have the potential to trigger HF by prostaglandin inhibition that leads to sodium and water retention, increased systemic vascular resistance, and blunted response to diuretics
- High-dose aspirin (greater than 325mg) should be avoided or withdrawn whenever possible
- AHA/ACC Heart Failure Guidelines; Circulation. 2016; 134

- **Warnings**
- You should not use aspirin if you have a bleeding disorder such as hemophilia, a recent history of stomach or intestinal bleeding, or if you are allergic to an NSAID (non-steroidal anti-inflammatory drug) such as Advil, Motrin, Aleve, Orudis, Indocin, Lodine, Voltaren, Toradol, Mobic, Relafen, Feldene, and others.

- Do not give this medication to a child or teenager with a fever, flu symptoms, or chickenpox. Salicylates can cause Reye's syndrome, a serious and sometimes fatal condition in children.

Pregnancy and Lactation

Use aspirin with caution during the first and second trimesters of pregnancy if benefits outweigh risks. Animal studies show risk and human studies not available or neither animal nor human studies done.

Use aspirin only in LIFE-THREATENING emergencies in the third trimester when no safer drug is available. There is positive evidence of human fetal risk. It is especially important that patient not use aspirin during last 3 months of pregnancy unless specifically directed to do so by doctor, because it may cause problems in unborn child or complications during delivery.

Aspirin enters breast milk; a decision should be made regarding whether to discontinue nursing or to discontinue drug, taking into account importance of drug to mother.

Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gauraipada, Vasai (E), Dist. Thane - 401 208. INDIA.
Tel. : 95250 - 2455801 / 2452714 / 2453525 • Fax : 95250 - 2452074 (0091 - 250 - 2452074) • Email : agog@vsnl.net & agogpharma@rediffmail.com

5. Pharmacological properties:

5.1 Pharmacokinetic Properties:

5.2 Pharmacodynemic Properties:

6. Pharmaceutical particulars:

6.1 List of Excipients:

Maize starch	BP
Borocin	BP
Cross Carmellose Sodium	BP
Colloidal silicon dioxide	BP
Purified talc	BP
Calcium Carbonate	BP

6.2 Incompatibilities:

None Reported

6.3 Shelf-Life:

36 months from the date of manufacture.

6.4 Special Precautions for Storage:

Store in a cool, dry and dark place. Protect from light.

6.5 Nature and Contents of Container:

1000 tablets packed in one Jar.

6.6 Special precautions for disposal:

None reported.

7. Registrant:

AGOG PHARMA LTD.
Plot No. 33, Sector II,
The Vasai Taluka Industrial
Co-Op. Estate Ltd., Gauraipada,
Vasai (E), Dist. Thane, India.

8. Manufacturer:

AGOG PHARMA LTD.
Plot No. 33, Sector II,
The Vasai Taluka Industrial
Co-Op. Estate Ltd., Gauraipada,
Vasai (E), Dist. Thane,
India.