



BUTAZOL

REGISTRATION NUMBER Q- 7972-094

Non-Steroidal Anti-Inflammatory Analgesic (NSAID) effective in relieving pain, reducing swelling, and increasing mobility in patients with rheumatic disorders.

FORMULATION:

Phenylbutazone 200 mg
Sodium salicylate... 13 mg
Vehicle q.s. 1 mL

DOSAGE SIZE AND FORM: 100 mL and 250 mL.
VETERINARY USE

SOLUTION FOR INJECTION

PHENYLBUTAZONE AND SODIUM SALICYLATE

NON-STEROIDAL ANTI-INFLAMMATORY AGENT WITH ANTIPYRETIC EFFECT

INDICATIONS:

BUTAZOL is a non-steroidal anti-inflammatory agent with analgesic and antipyretic effect, which inhibits the synthesis of prostaglandins that participate as chemical mediators of pain and inflammation. It plays an important role in the inhibition of cyclooxygenase which participates in the development of inflammatory, painful and febrile reactions.

BUTAZOL is effective in relieving pain, reducing swelling and tenderness, and increasing mobility in animal patients with rheumatic disorders. used in the treatment of traumatic arthritis, acute pulmonary infections, musculoskeletal conditions, dislocations, tendinitis, and trauma.

Description

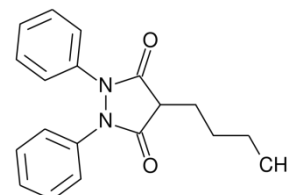
It is a non-steroidal antipyretic and anti-inflammatory analgesic (NSAID)

Molecular formula $C_{19}H_{20}N_2O_2$.

Chemical name: 17-ethynyl-13-methyl-7,8,9,

11,12,13,14,15,16,17-decahydro-6H-cyclopentane [a]phenanthrene-3,17-diol.

Molecular weight 308.37 g/mol.



**Mechanism of action:**

Inhibits arachidonic acid in the inflammatory cascade at the level of prostaglandin H synthetase and reduces the production of prostaglandins and thromboxane. Also inhibits the phagocytosis of urate crystals.

Pharmacology:

Phenylbutazone is a synthetic pyrazolone chemically related to aminopyrine; It is a white crystalline powder with a pK_a of 4.6, it is slightly soluble in water and alcohol. Provides good anti-inflammatory, analgesic, antipyretic, and uricosuric activity (increases uric acid excretion in the urine) by competitive inhibition of uric acid transport from the tubular lumen to the interstitium.

It is well absorbed in the digestive tract, small intestine and large intestine including the rectum, its bioavailability can be up to 94%, its effect is to inhibit the enzyme cyclooxygenase by inhibiting prostaglandins (PGE₂). It binds to plasma proteins (> 98%) and passes into the synovial fluid, where its concentrations reach 55-80% and persist up to 3 weeks after discontinuation of treatment. It crosses the placenta and is excreted in milk. The half-life in horses is 3.5 to 6 hours but is dose dependent. In horses and other species, it is early metabolized to oxyphenylbutazone and g-oxyphenbutazone. It is almost completely metabolized by oxidation and conjugation with glucuronic acid in the liver. It induces the activity of hepatic microsomal enzymes. Oxyphenbutazone has anti-inflammatory and analgesic activity. g-oxyphenbutazone has uricosuric activity. Its half-life is on average 77 hours. It is eliminated in the urine.

The half-life in horses is 3.5 - 7 hours and 6 - 12 hours in dogs, 40 hours or more in cows and 2 - 6 hours in pigs, it binds to plasma proteins up to 99% and can displace other drugs such as sulfa drugs or penicillin.

Being an NSAID, it inhibits stomach and kidney prostaglandins, so it should not be dosed for prolonged periods, nor in weak animals. The lesions that predominate the gastro-intestinal tract range from small erosions to ulcerations in the colon and cecum; renal papillary necrosis has also been reported.

Sodium salicylate is a weak acid that, after being absorbed, is hydrolyzed to salicylic acid, most of which is in the ionized form (99%). It is extensively bound to albumin, rapidly distributed to synovial, cerebrospinal, and peritoneal fluid, saliva, and milk, excreted primarily in the urine. In the liver these are biotransformed mainly to salicyluric acid (conjugated with glycine), phenolic glucuronide and acyl glucuronide, and excreted in this form together with 10% as free salicylic acid. The half-life is on average 1 hour.



Sodium salicylate is a structural analog of acetylsalicylic acid; It has an analgesic, antipyretic, and anti-inflammatory effect. It relieves pain by providing an anti-inflammatory effect directly, by inhibiting prostanoid synthesis, or indirectly by inhibiting certain transcription factors such as NF- κ B and AP-1 that alter cellular kinases. It acts on the hypothalamic temperature regulating center. The analgesic effect is potentiated thanks to the association that exists between the effect of Phenylbutazone and Sodium Salicylate.

Drug-Drug Interactions:

As it is highly bound to plasma proteins, it can displace other drugs such as fenthion, valproic acid, oral anticoagulants, other anti-inflammatory agents, sulfonamides, and penicillins, among others. It may increase the half-life of Penicillin G or lithium. Phenylbutazone can antagonize the increased renal blood flow effect caused by furosemide.

Withdrawal period:

Do not administer to horses intended for human consumption.
Do not use milk from treated animals until after 4 - 5 milkings.

Warnings:

- Do not use this product before slaughtering animals intended for human consumption. Protect it from sunlight. Keep it in a cool, dry place and out of reach of children. Product for exclusive use in veterinary medicine.
- Do not co-administer **Butazol**[®] with another drug product as the risk of potentiation may be increased due to the strong binding capacity of phenylbutazone to plasma proteins (> 96%).
- Do not administer **Butazol**[®] within 6 weeks before therapy or after therapy with coumarin anticoagulants (for example, warfarin).
- It is not recommended to use it in foals with a high parasite load or malnourished.
- Regular monitoring of total serum or plasma protein allows to know if it is necessary to reduce the dose or discontinue therapy.
- In acute conditions, a dose of 8.8 mg per kg per day is used, for a period of 3 days and subsequently a dose of 4.4 mg per kg per day is recommended to use.
- The combination of phenylbutazone with another NSAID (Flunixin meglumine) must be carefully managed to avoid toxicity. This is a veterinary product; it is not suitable for use in humans (it can cause aplastic anemia and gastrointestinal ulcers).
- Keep out of reach of children.

Butazol[®] may be used in:

- Bursitis, tendon, and joint acute synovitis.
- Acute joint and ligament strains, tendon sprains.
- Serous arthritis and concomitantly with antibiotics in infectious arthritis.
- Control of soft tissue reaction following surgical procedures, including castration.
- Control of inflammation in tissue contusions and abrasions.
- As aid in the relief of pain related to arthritic, acute and chronic conditions.
- Analgesic, anti-inflammatory therapy in the treatment of acute and chronic laminitis.

**Species:**

Equines (Not intended for human consumption)

BUTAZOL Dose:

1 mL per 50 kg of body weight (equivalent to 4 mg per kg of body weight of phenylbutazone) every 24 hours for 3 to 5 days.

ROUTE OF ADMINISTRATION:

Slow intravenous route.

WARNINGS AND/OR RESTRICTIONS:

Do not administer to equines intended for human consumption. The injectable preparation should not be administered intramuscularly or subcutaneously, as it is highly irritating. Intracarotid injections can cause central nerve stimulation and seizures. Therapy should be discontinued at the first signs of any toxic reaction (for example, anorexia, oral lesions, depression, decreased plasma protein, increased serum creatinine, leukopenia, or anemias). Do not use in pregnant animals. Keep in a cool, dry place, in a range within 15-30 °C and protected from direct sunlight. Keep out of reach of children and pets. Shake well before use. Product for exclusive use in Veterinary Medicine.

Consult a Doctor of Veterinary Medicine.

Available by prescription only.

Exclusive literature for Doctors of Veterinary Medicine.

Responsible for content: Technical department.