



Anastrozol-HAEMATO

1 mg / 30 film-coated tablets

Pharmacotherapeutic group:

Enzyme inhibitors (cytostatic agent)

Active substance:

Anastrozole

List of excipients:

Core of the tablet:

lactose monohydrate, sodium starch glycolate (type A) (Ph.Eur.), povidone (K25), magnesium stearate (Ph.Eur.) [herbal]

Film-coating:

hypromellose, macrogol 6000, hydrogenated cotton seed oil, modified starch (maize), titanium dioxide (E171)

PZN:

7767555

Therapeutic indications:

Treatment of advanced hormone-receptor-positive breast cancer in post-menopausal women

Composition:

Each film-coated tablet contains 1 mg anastrozole as active substance.

Other excipients:

Tablet core: lactose monohydrate, sodium starch glycolate (type A) (Ph.Eur.), povidone (K 25), magnesium stearate (Ph.Eur.) [herbal]

Coating: hypromellose, macrogol 6000, hydrogenated cotton seed oil, modified starch (maize), titanium dioxide (E171)

4. Therapeutic indications:

Treatment of advanced hormone-receptor-positive breast cancer in post-menopausal women.

5. Contraindications:

- pregnancy or breast-feeding
- known hypersensitivity to anastrozole or to any of the excipients

6. Possible side effects

Very common side effects (seen in more than 1 in 10 patients):

- headache
- hot flushes
- nausea
- rash
- joint pain/stiffness
- arthritis
- asthenia
- decrease in bone density (osteoporosis)



Common side effects (seen in 1 to 10 in 100 patients):

- anorexia (loss of appetite),
- raised levels of cholesterol
- somnolence
- Carpal tunnel syndrome
- diarrhoea
- vomiting
- changes in laboratory values of liver enzymes (raised levels of gamma-GT and alkaline phosphatase)
- hair thinning (hair loss)
- allergic reactions
- bone pain
- vaginal dryness
- vaginal bleeding

Uncommon side effects (seen in 1 to 10 in 1,000 patients):

- increases in gamma-GT and bilirubin
- inflammation of the liver (hepatitis)
- skin rash or urticaria
- trigger finger

Rare side effects (seen in 1 to 10 in 10,000 patients):

- skin reactions with redness and blistering
- skin rash caused by allergic reactions
- inflammation of small blood vessels that causes palpable purpura; often with joint, abdominal and kidney pain (Schönlein-Henoch purpura).

Very rare side effects (seen in less than 1 in 10,000 patients)

- changes of the skin with blistering (Stevens-Johnson syndrome)
- allergic reactions, including swelling of the skin and mucosa, hives and acute hypersensitivity reactions (angioedema)

7. Special warnings

This product contains lactose monohydrate. Read the package leaflet before use.
Keep out of the reach and sight of children.

8. Medicinal product subject to medical prescription.

Date of revision: 06/2012