

## Safety Alert

Nov. 2025

### Benzdamine– Risks of systemic use during the third trimester in pregnancy

EDA performs label update to include the following:

#### **Fertility, Pregnancy and lactation**

There are no clinical data from the use of benzydamine during pregnancy.

During the third trimester of pregnancy, systemic use of prostaglandin synthetase inhibitors may induce cardiopulmonary and renal toxicity in the fetus. At the end of the pregnancy prolonged bleeding time in both mother and child may occur, and labour can be delayed.

It is not known if the systemic benzydamine exposure reached after topical administration can be harmful to an embryo/fetus.

Therefore, benzydamine should not be used during pregnancy unless clearly necessary. If used, the dose should be kept as low and duration of treatment as short as possible.

#### **Background:**

The systemic use of Benzydamine during the third trimester of pregnancy (typically starting around 20 to 30 weeks of gestation) is strongly discouraged and generally considered contraindicated by regulatory bodies and healthcare guidelines.

This strict caution is because Benzydamine is a prostaglandin synthetase inhibitor (a type of Non-Steroidal Anti-Inflammatory Drug, or NSAID), and systemic exposure to this class of drugs in late pregnancy poses significant risks to the developing fetus.

The risks stem from the interference of Benzydamine with the essential role of prostaglandins in fetal circulation and renal function.

##### **1. Cardiopulmonary Toxicity**

Premature Constriction/Closure of the Ductus Arteriosus (DA): This is the most critical risk. The DA is a vital blood vessel that bypasses the fetal lungs. Prostaglandins keep it open before birth. Systemic NSAID exposure causes the DA to narrow or close prematurely.

Consequence: This results in high blood pressure in the fetal lungs (Pulmonary Hypertension) and can lead to right-sided heart failure in the fetus.

##### **2. Fetal Renal Toxicity**

Fetal Renal Dysfunction: Systemic NSAIDs inhibit the prostaglandins necessary for maintaining adequate blood flow and function in the fetal kidneys.

Consequence: This leads to a severe reduction in fetal urine output. Since fetal urine is the primary source of amniotic fluid in late pregnancy, this results in Oligohydramnios (low amniotic fluid).

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### 3. Maternal and Neonatal Risks

**Delayed Labor:** By inhibiting prostaglandins, Benzydamine can suppress uterine contractions, potentially delaying the onset or progress of labor.

**Increased Bleeding Risk:** NSAIDs can inhibit platelet aggregation, leading to a risk of prolonged bleeding time for both the mother and the newborn during delivery.

### Therapeutic Indication

Benzydamine is a locally-acting non-steroidal anti-inflammatory drug (NSAID) with local anesthetic and analgesic properties. It is primarily used for the symptomatic relief of pain and irritation in the mouth and throat.

- Oromucosal (Mouth, Throat, and Gums) Conditions (mouthwash, spray, lozenges)
- Musculoskeletal Pain (Creams/Gels)
- Gynecological/Vaginal Inflammation (Vaginal Wash/Solution)

### Reference

EMA ([click Here](#))