



# ARTWORK RECORD

<b>Colour</b>  	<b>Product</b> : <b>Throzz Bromhexine 8 mg</b>	Language : English
	<b>Generic Name</b> : <b>Material</b> : <b>Insert</b> <b>Size</b> : <b>137 L x 208 H mm</b> <b>Pack size</b> : <b>50x10 Tab</b> <b>Date</b> : <b>19-05-2026</b> <b>A/W Code</b> : <b>52876101-00</b> <b>Revision No.</b> :	<b>Country : Malaysia</b>
<b>Reason for Revision :</b>		<b>Note:</b>

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<p><b>THROZZ Bromhexine 8mg Tablet</b></p> <p><b>NAME AND STRENGTH OF ACTIVE SUBSTANCE</b> Each uncoated tablet contains: Bromhexine Hydrochloride 8mg.</p> <p><b>DESCRIPTION</b> White to off white, round tablet, bevel-edged on one side and break-line on other side.</p> <p><b>PHARMACODYNAMICS/MECHANISM OF ACTION</b> Pharmacotherapeutic group: Mucolytics, ATC code: R05CB02</p> <p>Bromhexine hydrochloride is a mucolytic expectorant whose action is to stimulate the mucous glands to produce a secretion which is less viscous and has a reduced content of acid glycoprotein fibers.</p> <p><b>PHARMACOKINETICS</b> Bromhexine hydrochloride is rapidly absorbed from the gastrointestinal tract and about 85% to 90% of a dose is excreted in the urine mainly as metabolites. Ambroxol is a metabolite of bromhexine. Bromhexine is highly bound to plasma proteins.</p> <p><b>INDICATION</b> For the reduction of sputum viscosity.</p> <p><b>RECOMMENDED DOSAGE</b> Adults: 8-16 mg (1 – 2 tablet), 3 – 4 times daily. Children: 5 – 10 years: 4 mg (1/2 tablet) 3 times daily. Under 5 years: 4 mg (1/2 tablet) 2 times daily.</p> <p><b>ROUTE OF ADMINISTRATION</b> Oral</p> <p><b>CONTRAINDICATIONS</b> Hypersensitivity to Bromhexine hydrochloride.</p> <p><b>WARNING AND PRECAUTIONS</b> Since mucolytics may disrupt the gastric mucosal barrier, bromhexine hydrochloride should be used with caution in patients with a history of gastric ulceration. Very rare cases of chronically associated severe skin impairments such as Stevens Johnson Syndrome, Toxic Epidermal Necrolysis (TEN), Erythema Multiforme (EM) and Acute Generalized Exanthematous Pustulosis (AGEP) have been reported. In most cases, these could be explained by the severity of the underlying disease or concomitant administration of another drug. In the early stages of such severe skin reactions, initially only nonspecific flu-like symptoms appear, e.g. fever, arthralgia, runny nose, cough, and sore throat. If skin or mucous membrane damage occurs, seek medical advice immediately and discontinue treatment as a precaution.</p> <p><b>INTERACTIONS WITH OTHER MEDICINES</b> Bromhexine hydrochloride has been shown to enhance the response of erythromycin, cephalixin and amoxicillin.</p> <p><b>PREGNANCY AND LACTATION</b> It is advisable to avoid use during the first three months of pregnancy and during lactation. Bromhexine hydrochloride is excreted in breast milk.</p> <p><b>SIDE EFFECTS</b> Occasional gastrointestinal discomfort may occur, but there are almost invariably mild. There may be a transitory</p>

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<p>rise in serum transaminases levels in some patients. With continuation of the drug, transaminases return pretreatment levels, even in those patients with pre-existing impairment of hepatic function.</p> <p><i>Immune System Disorders:</i> Frequency not known: Anaphylactic reactions including anaphylactic shock.</p> <p><i>Skin and Subcutaneous Skin Disorders:</i> Frequency not known: Severe skin reactions (including Stevens Johnson syndrome, Toxic epidermal necrolysis (TEN), Erythema Multiforme (EM) and Acute Generalized Exanthematous Pustulosis (AGEP)</p> <p><b>SYMPTOMS AND TREATMENT OF OVERDOSAGE</b> Cases of over dosage, if occur, should be managed symptomatically.</p> <p><b>PRESENTATION</b> Blister of 10 tablets. Box of 10 blisters, 50 blisters, 100 blisters</p> <p><b>STORAGE CONDITION</b> Store below 30°C</p> <p><b>SHELF LIFE</b> The expiry date of this pack is printed on the box. Do not use this pack after this date.</p> <p><b>PRODUCT REGISTRATION HOLDER</b> Medicinspire Global Sdn Bhd B-5-28, Ativo Plaza, No.1, Jalan PJU 9/1, Damansara Avenue, Bandar Sri Damansara, 52200 Kuala Lumpur, Malaysia</p> <p><b>MANUFACTURED BY:</b> SAGA LIFESCIENCES LIMITED Survey No. 198/2 &amp; 198/3, Chachrawadi Vasna, Tal.: Sanand, Dist.: Ahmedabad 382210 India</p> <p>MAL 26056033XZ Date of Revision: 16 January 2026 Artwork No.: 52876101-00</p>
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