



# ALPRAZOLAM

0.25 mg, 0.5 mg, 1 mg tablets

## PROFILE

<b>Classification</b>	Medicinal product, Rx
<b>ATC code (3<sup>rd</sup> level)</b>	N05B anxiolytics
<b>Dosage form</b>	Tablets
<b>Active ingredients</b>	0.25 mg, 0.5 mg, 1 mg alprazolam
<b>Therapeutic indication</b>	<ul style="list-style-type: none"><li>• For short-term symptomatic treatment of anxiety in adults</li><li>• Indicated only when the disorder is severe, disabling or subjecting the individual to extreme distress</li></ul> <i>*subject to approval by the National Competent Authorities</i>
<b>Reference medicinal product</b>	Xanax 0.25 mg, 0.5 mg, 1 mg tablets MAH: Upjohn EESV (previously Pfizer)

## DEVELOPMENT / PRODUCTION STATUS

<b>Packaging</b>	Blister (PVC/PVdC/Al foil) contains 10 tablets
<b>Pack size</b>	30 and 90
<b>Batch size (MOQ)</b>	0.25 mg: 116 000 or 464 000 tablets 0.5 mg: 116 000 or 464 000 tablets 1 mg: 116 000 or 464 000* tablets <i>*possible scale up</i>
<b>Shelf life</b>	3 years
<b>Additional available stability data</b>	Climate zone IVb (PVC/PVdC/Al foil) 24 months

## AVAILABLE DOSSIER

CTD/eCTD

## AVAILABLE MARKETING AUTHORIZATIONS

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## BUSINESS MODEL

- License and supply
- License and supply with transfer of granted MA
- Distribution model

## COMPETITIVE EDGE / CLAIM

- One of the most prescribed drugs for anxiety in the world
- Safety profile and proven efficacy