



ALPRAZOLAM

0.25 mg, 0.5 mg, 1 mg tablets

PROFILE

Classification	Medicinal product, Rx
ATC code (3rd level)	N05B anxiolytics
Dosage form	Tablets
Active ingredients	0.25 mg, 0.5 mg, 1 mg alprazolam
Therapeutic indication	• For short-term symptomatic treatment of anxiety in adults • Indicated only when the disorder is severe, disabling or subjecting the individual to extreme distress <i>*subject to approval by the National Competent Authorities</i>
Reference medicinal product	Xanax 0.25 mg, 0.5 mg, 1 mg tablets MAH: Upjohn EESV (previously Pfizer)

DEVELOPMENT / PRODUCTION STATUS

Packaging	Blister (PVC/PVdC/Al foil) contains 10 tablets
Pack size	30 and 90
Batch size (MOQ)	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>
Shelf life	3 years
Additional available stability data	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