

Public assessment summary report

Name of the Finished Pharmaceutical Product	Minox 5, 50 mg/ml, cutaneous solution
Manufacturer of the Finished Product	LABORATORIO EDOL - PRODUCTOS FARMACEUTICOS, S.A AVENIDA 25 DE ABRIL, 6 - 6 A, 2795-225 LINDA-A-VELHA, PORTUGAL
License holder	Laboratório Edol - Produtos Farmacêuticos S.A. Av. 25 de Abril, 6-6A 2795-225 Linda-a-Velha Portugal Phone: +351 21 415 81 30 Fax: +351 21 415 81 31 e-mail: geral@edol.pt
Active Pharmaceutical Ingredient (API)	Minoxidil

1. Introduction

Based on review of quality, safety and efficacy data through the abbreviated approval procedure, the authority granted a marketing authorization for MINOX 5.

Minox 5 is a clear, colourless or lightly yellow cutaneous solution with an alcoholic odour. Each milliliter of the cutaneous solution contains 50 mg of minoxidil.

Minox 5 is intended for external use only, with an application on the scalp, twice daily (12/12h), on completely dry hair.

2. Assessment of quality

GMP compliance of the API manufacture was demonstrated by document review. The necessary waiver for cGMP of the finished pharmaceutical product manufacturer has been carried out. Marketing authorization was granted by the stringent regulatory authority (SRA) and appropriate verification of marketing authorization was performed.

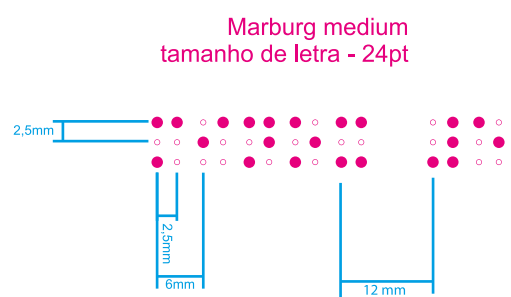
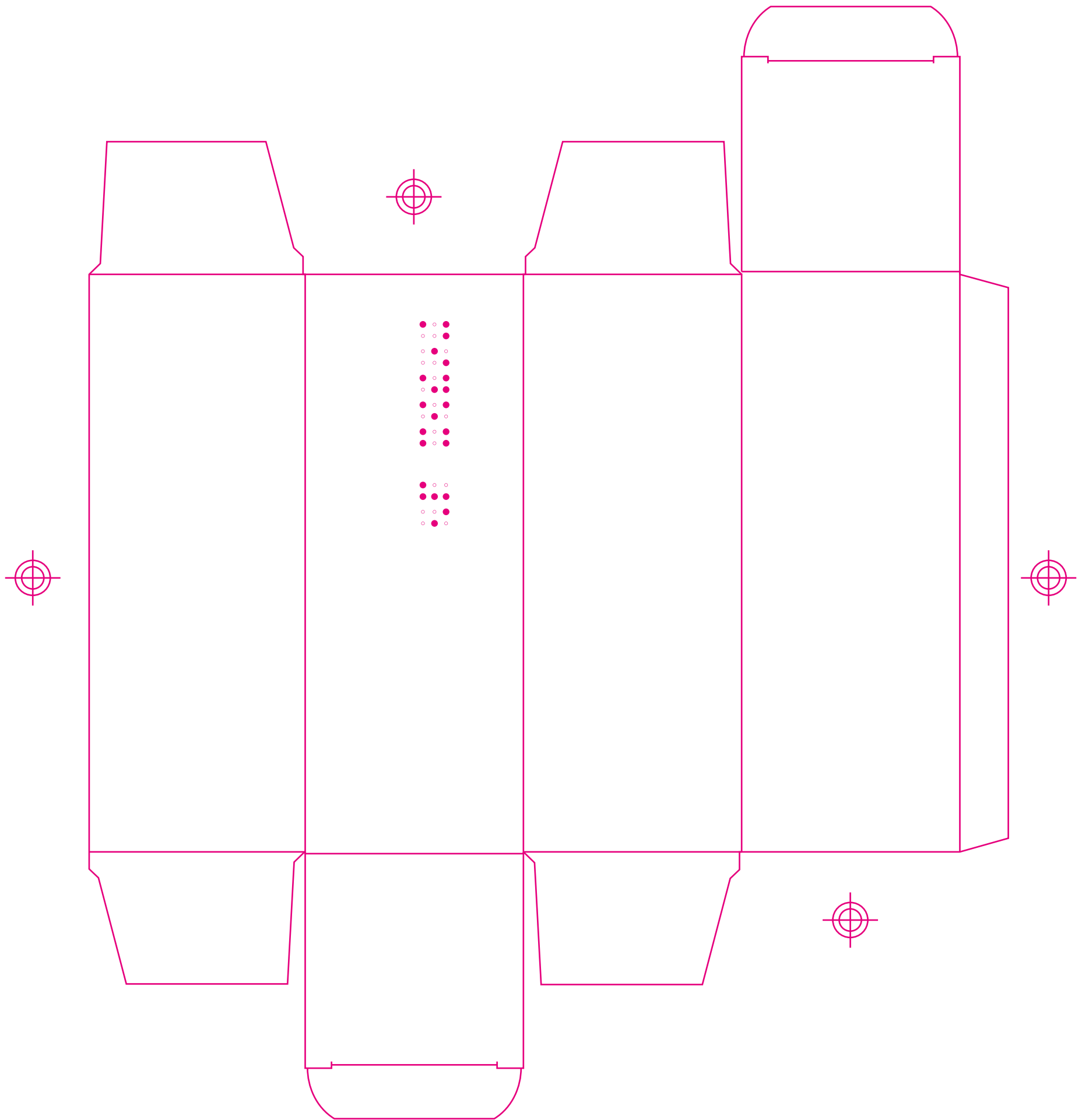
Stability testing:

It is confirmed that the finished product stability studies were conducted in the container closure system proposed for the marketing of the product in accordance with the current medicine registration guideline of Ethiopia. The packaged product was stored at the long term condition of 30°C/75% RH and at the accelerated condition of 40°C/75% RH. The packaging


components used are the same as those for proposed commercial package for the marketed product. Based on the data presented, shelf life of 36 months was proposed.

3. Conclusion

Based on assessment of administrative and technical document, it is considered that the benefit–risk profile of Minox 5, 50 mg/ml, cutaneous solution manufactured by laboratório edol - produtos farmaceuticos, s.a avenida 25 de abril, 6 - 6 a, 2795-225 linda-a-velha, portugal is acceptable for the following indications: treatment of male and female baldness, known as androgenic alopecia; treatment of alopecia areata, also known as spot baldness.



minox #5

 saúde que se vê	Laboratório Edol – Produtos Farmacêuticos S.A.
	Minoxidil 50 mg/ml cutaneous solution
Module 1	Administrative Information and Prescribing Information
Module 1.7.	Product Information

➤ **Immediate label**



ampliado 200%

DRE

DRE

DCQ

GP

Rótulo Minox5 Exportação
100 ml



[45 x 64 mm]



verniz localizado



reserva



cortante



braille



[cores: 4 cores directas - pantone]

LAETUS CODE

CÓD. AIM:

CÓD. PRODUTO:

Não serve como prova de cor

data 29/04/15 prova ATF 1
06/10/15 AF 2

Efectuar
correções

Textos ☐
Cores ☐
Formato ☐
Códigos ☐
Braille ☐
Verniz ☐

Aprovação
pelo Cliente

Não Aprovado

Aprovado

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