[redacted]

[redacted]

A graduated oral dosing syringe is provided with the product to facilitate administration across the wide recommended dosing range.

[redacted]

"In-use" note: The LDPE adaptor remains attached to the bottle throughout the in-use shelf life of the product (maximum 7 weeks proposed). The CRC cap is therefore replaced over the top of the adaptor after first use of the product.

	Vol-page Summary	*Vol-page Full report*

[redacted]

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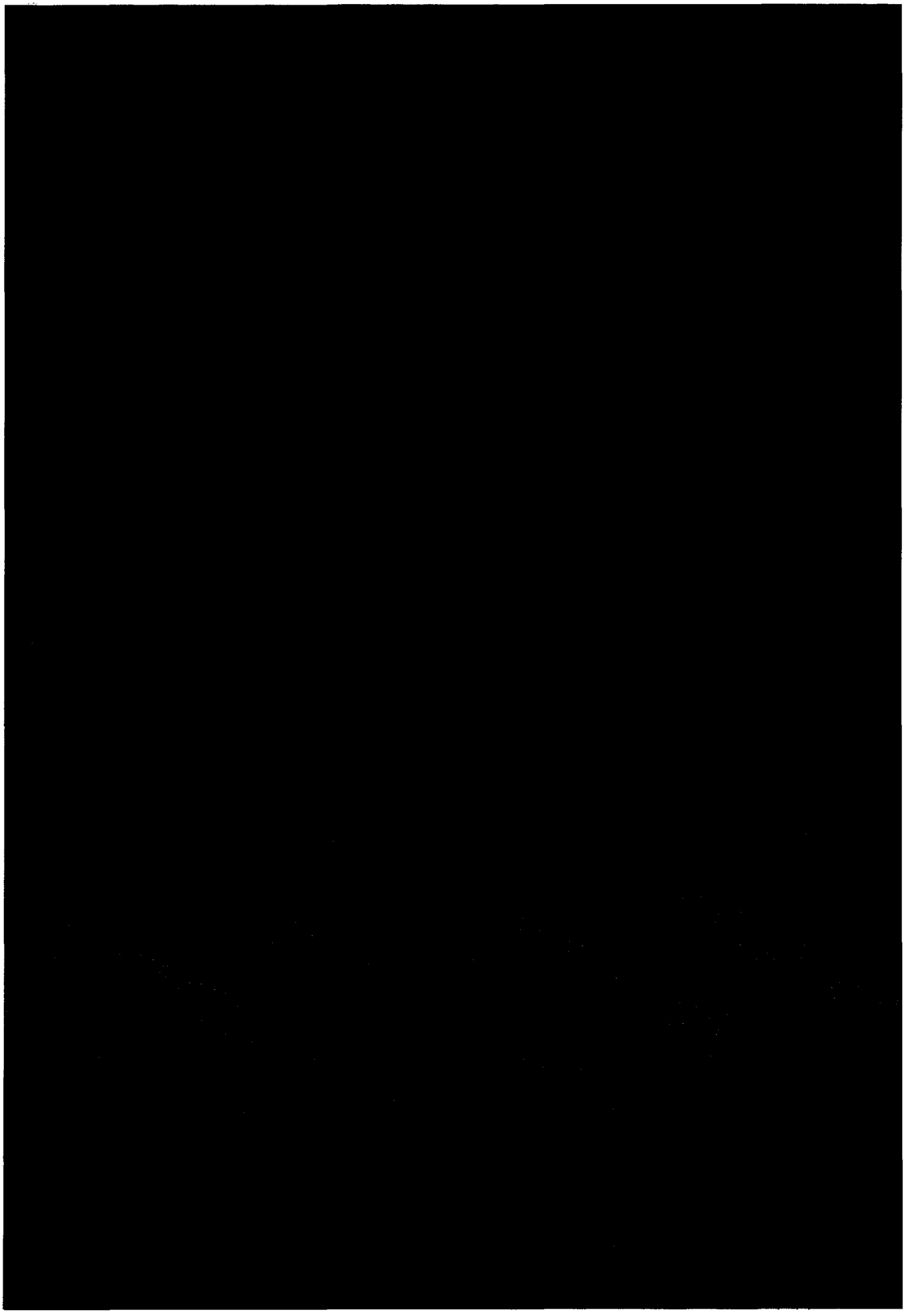

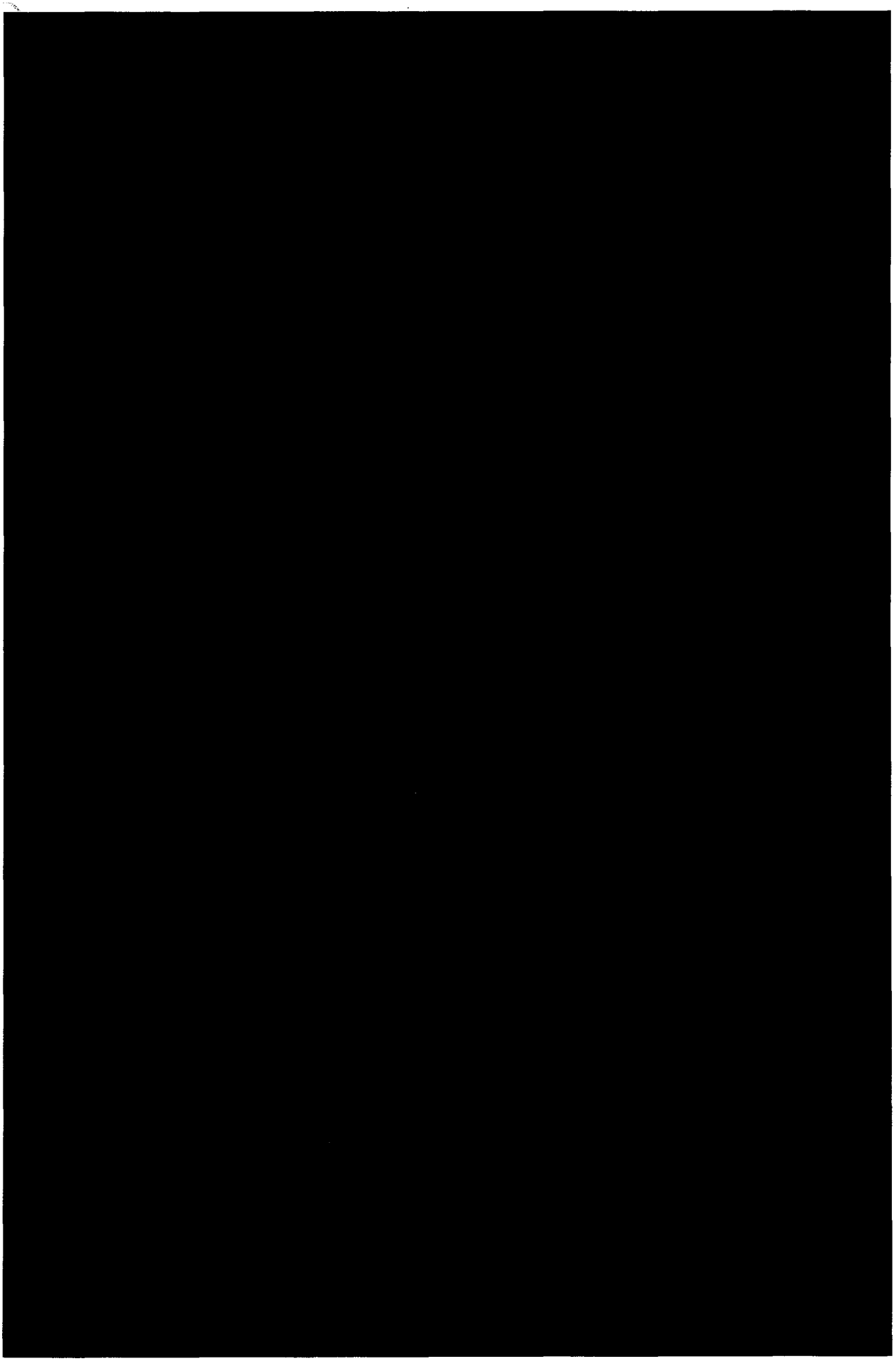

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3.3. Packaging materials (immediate packaging)

A standard brown glass bottle (300 ml) with a child resistant, polypropylene closure was selected as the primary packaging. The glass is hydrolytic resistance type III according to the European Pharmacopoeia. *2B116A, 44-51*

For precise dosage the following administration accessories will be included in the secondary packaging along with the medicinal product:

A 10-ml graduated polypropylene oral dosing syringe

A low density polyethylene press-in bottle adaptor

The oral dispenser has been classified as a Class I device with measuring function according to the EC Council Directive 93/42/EEC Article 11 section 5 and Annex VII, and measuring function requirements of Annex V. The dispenser has been CE marked accordingly.

The bottle adaptor has been classified as a Class I device according to the EC Council Directive 93/42/EEC Article 11 section 5 and Annex VII. The bottle adaptor has been CE marked accordingly.

Both the immediate packaging and the administration accessory are considered appropriate for worldwide use. The materials are tested according to internal

[redacted]

Novartis Testing Monographs which ensure their suitability before use. In addition to the routine testing parameters performed on the glass bottle, both chemical resistance and light transmission tests are carried out according to USP on at least the first three batches delivered. These USP tests are almost identical to those defined in the European Pharmacopoeia and lead to the same conclusions. The USP tests were selected to facilitate the global registration of the product.

The packaging components and the administration accessories have been shown to be compatible with the drug product. The oral dispenser has been proven to perform correctly throughout the maximum in-use period (7 weeks) recommended for the product.

[redacted]

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