Saudi Public Assessment Report

(Summary Report)

Loanta®

Type of Application: New Drug Application.

Type of Product: Human Generic Drug.

Active Pharmaceutical Ingredient(s): Baclofen

ATC code: M03BX01

Dosage Form: Tablet

Dosage Strength: 10 mg

Pack Size: 50

Shelf life: 24 months

Storage Conditions: Store below 30°C

Reference Product in SA (if applicable): Lioresal

Marketing Authorization Holder: Alpha Pharma Industry

Note: The Saudi PAR is a final document, which provides information relating to a submission at a particular point in time and will not be updated after publication.

Manufacturer: Alpha Pharma Industry

Registration No.: 0802244868

Date of Decision: 07/02/2024

Proposed Indications:

Baclofen is indicated for the relief of spasticity of voluntary muscle resulting from such disorders as multiple sclerosis, other spinal lesions e.g. tumours of the spinal cord, syringomyelia, motor neurone disease, transverse myelitis, traumatic partial section of the cord.

Baclofen is also indicated in adults and children for the relief of spasticity of voluntary muscle arising from e.g. cerebrovascular accidents, cerebral palsy, meningitis, traumatic head injury. Patient selection is important when initiating baclofen therapy; it is likely to be of most benefit in patients whose spasticity constitutes a handicap to activities and/or physiotherapy. Treatment should not be commenced until the spastic state has become stabilized.

Paediatric population

Baclofen is indicated in patients 0 to <18 years for the symptomatic treatment of spasticity of cerebral origin, especially where due to infantile cerebral palsy, as well as following cerebrovascular accidents or in the presence of neoplastic or degenerative brain disease.

Baclofen is also indicated for the symptomatic treatment of muscle spasms occurring in spinal cord diseases of infectious, degenerative, traumatic, neoplastic, or unknown origin such as multiple sclerosis, spastic spinal paralysis, amyotrophic lateral sclerosis, syringomyelia, transverse myelitis, traumatic paraplegia or paraparesis, and compression of the spinal cord.

Product Background

This product is considered as a human generic drug for Saudi regulatory purposes qualified to follow the SFDA's regulatory Regular pathway.

The SFDA approval for Loanta® is based on a review of the quality, safety and efficacy of the product provided as an e-CTD in accordance with the relevant guidelines, basic product information summarized hereinafter:

Drug Substance

- Baclofen is a white or almost white powder, odorless or practically odorless. Baclofen is slightly soluble in water, very slightly soluble in methanol and in 96% ethanol, practically insoluble in acetone, insoluble in chloroform, dissolves in dilute mineral acids and in dilute solutions of alkali hydroxides. Polymorphism has been observed (Form B).
- The drug substance is manufactured by a multiple-step chemical synthesis.
- The structure of the API has been fully elucidated using several spectroscopic techniques.
- The drug substance specification includes relevant tests for proper quality control. Whereas the control methods are validated according to international guidelines.
- Appropriate stability data have been presented and justify the established re-test period.

Drug Product

- The finished product is available as tablets. Each tablet contains 10 mg of Baclofen. The composition of the drug product is adequately described, qualitatively and quantitatively. Suitable pharmaceutical development data have been provided for the finished product composition and manufacturing process.
- The manufacturing process is described narratively and in sufficient detail, taking into account pharmaceutical development data. Batch manufacturing formulas and in-process controls are included.
- The drug product specification covers appropriate parameters for this dosage form which allow for proper control of the finished drug product. The control methods are validated according to international guidelines. Batch data show consistent quality of the drug product.
- The drug product is packaged in (Alu – PVC/PE/PVDC blister).
- Appropriate stability data have been generated in the packaging material intended for commercial use and following relevant international guidelines. The data show good stability of the finished product and support the shelf life.

Clinical Aspects

Bioequivalence Study

Ratio and 90% Confidence Intervals (CI) of Loanta® (Baclofen) 10 mg versus Lioresal® (Baclofen) 10 mg Tablets:

Pharmacokinetic Parameter	**Point Estimate**	**90% CI**
C_{max}	103.85	99.33 - 108.59
AUC_{0-t}	104.23	101.18 - 107.38
$AUC_{0-\infty}$	104.19	101.40 - 107.05

Based on the results obtained in this study, Loanta® (Baclofen) 10 mg of Alpha pharma industries, Saudi Arabia, is **bioequivalent** to Lioresal® (Baclofen) 10 mg of Novartis Pharma S.p.A., Torre Annunziata, Italy under fed Conditions.

Product Information

The approved Summary of Product Characteristics (SPC) with the submission can be found in Saudi Drug Information System (SDI) at: https://sdi.sfda.gov.sa/

The date of revision of this text corresponds to that of the Saudi PAR. New information concerning the authorized medicinal product in question will not be incorporated into the Saudi PAR. New findings that could impair the medicinal product's quality, efficacy, or safety are recorded and published at (SDI or Summary Saudi-PAR report).

For inquiry and feedback regarding Saudi PAR, please contact us at Saudi.PAR@sdfa.gov.sa