

File No. 1-1709/FSSAI/Imports/2017 (Part-1)
Food Safety and Standards Authority of India
(A Statutory Authority under the Ministry of Health and Family Welfare, Govt. of India)
FDA Bhawan, Kotla Road, New Delhi-110002

Dated, The 07th Dec, 2017

8th

ORDER

Subject: Discontinuation of previously approved label and introduction of new/updated label of the product Milupa OS 1-Reg.

In partial modification to the Direction issued vide even no. dated 12.06.2017 regarding Import of Specialty Foods for IEM disorders issued by FSSAI, one of the label previously approved for the IEM product i.e. Milupa OS 1 of M/s Nutricia International is discontinued and the new label (i.e. Nutricia Milupa OS 1) is introduced. The copy of substituted (new) label is attached for reference & further necessary action.

This issues with the approval of the Competent Authority.

(S.K Yadav)
Director (Imports)

Enclosures: as above

To,

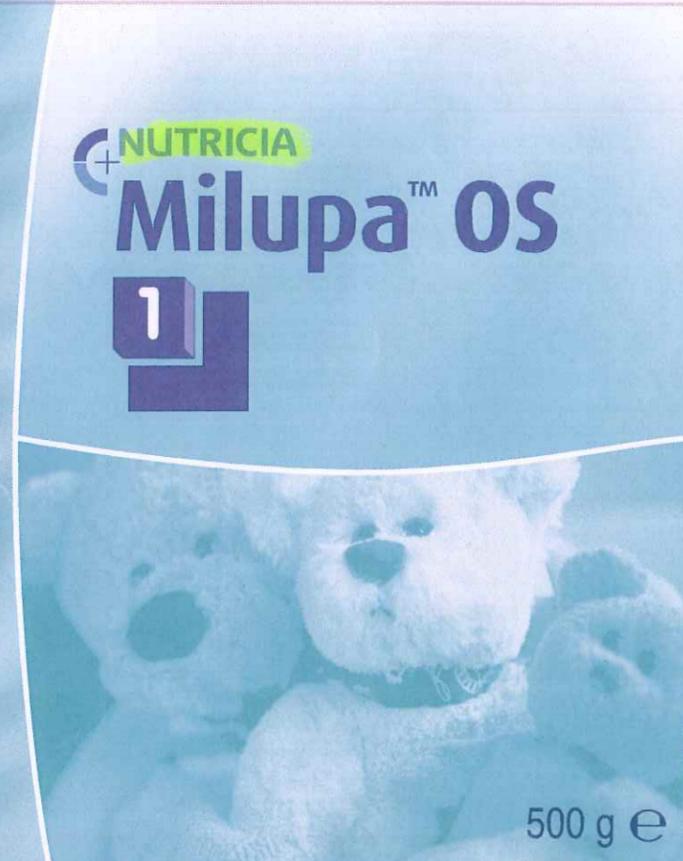
1. The Authorized Officer (Mumbai & Delhi)

Copy for information to:

1. PPS to Chairperson, FSSAI
2. PS to CEO, FSSAI
3. Advisor (Standards)

V=+109.
H=+325.

7



NUTRICIA
Milupa™ OS

1

500 g e

EN Food for special medical purposes. For the dietary management of organic acidemia i.e. methylmalonic acidemia and propionic acidemia in infants. An isoleucine, methionine, threonine and valine-free powdered mixture of amino acids with carbohydrate, vitamins, minerals and trace elements.

Important notice: For enteral use only. Must be used under medical supervision. Not suitable as a sole source of nutrition. Suitable for infants. Only to be used by individuals with organic acidemia.

Storage: Store unopened product in a cool, dry place. For additional information prior to use please see attached leaflet.

Produced in the EU
Best before: see base of can.

DE Diätetisches Lebensmittel für besondere medizinische Zwecke (Bilanzierte Diät). Zur diätetischen Behandlung von Säuglingen im 1. Lebensjahr mit Organozidopathien (z.B. Methylmalonazidurie, Propionazidurie), CH: Für die besonderen Ernährungsbedürfnisse bei Organozidopathien. Eine isoleucin-, methionin-, threonin- und valinfreie Aminosäuremischung, bedarfsgerecht angereichert mit Vitaminen, Mineralstoffen und Spurenelementen.

Wichtige Hinweise: Nur unter ärztlicher Aufsicht verwenden. Für Säuglinge im 1. Lebensjahr mit Organozidopathien. Nicht zur ausschließlichen Ernährung geeignet. Nur zur enteralen Ernährung geeignet.

Gebrauchsanweisung: Ungeöffnet kühl und trocken lagern. Für weitere Informationen: siehe Booklet.
PZN: 02557358

Hergestellt in der EU.

Vertrieb in Deutschland und Österreich: Nutricia GmbH, D-91015 Erlangen, Deutschland.
Vertrieb in der Schweiz: Nutricia SA, CH-1564 Domdidier, Schweiz.
Kontakt Nutricia Metabolics Deutschland, Österreich, Schweiz:
Tel. 00 800 - 747 737 99 • www.nutricia-metabolics.info

Mindestens haltbar bis: L-Nr.: siehe Dosenboden.

NL Dieetvoeding voor medisch gebruik. Bij de deeltbehandeling van organische acidemie, zoals methylmalonacidemie en propionacidemie bij zuigelingen. Een isoleucine-, methionine-, threonine- en valinevrije poedervormige mix van aminozuren met koolhydraten, vitamines, mineralen en sporenelementen.

Belangrijke mededeling: Alleen voor enteraal gebruik. Uitsluitend te gebruiken onder medisch toezicht. Niet geschikt als enige voedingsbron. Geschikt voor zuigelingen. Uitsluitend te gebruiken door patiënten met organische acidemie.

Bewaaraadvies: Ongeopend product bij voorkeur op een koele, droge plaats bewaren. Zie, voorafgaand aan gebruik, aangehecht label voor meer informatie.

Geproduceerd in de EU

Nutricia Nederland B.V., Antwoordnummer 10230, 2700 VB Zoetermeer, NL.
Nutricia Medische Voedingservice: 0800-022 33 22 (gratis), www.nutriciamedischevoeding.nl
N.V. Nutricia, Romeinsesteenweg, 564C, 1853 Strombeek-Bever, België.
Voor meer informatie: 070222307, medical.nutrition@nutricia.be - www.nutricia.be

Ten minste houdbaar tot: zie onderzijde blik.

FR Aliment diététique destiné à des fins médicales spéciales. Pour le traitement diététique d'acidémies organiques telles que l'acidémie méthylmalonique et propionique chez les nourissons. Mélange équilibré d'acides aminés essentiels et non essentiels sous forme de poudre sans isoleucine, méthionine, threonine et valine, et contenant des glucides, des vitamines, des minéraux et des oligoéléments.

Avis important : Usage entéral exclusif. A utiliser sous contrôle médical. Ne convient pas comme seule source d'alimentation. Convient aux nourissons. Ne doit être utilisé qu'en cas d'acidémies organiques telles que l'acidémie méthylmalonique et propionique.

Conservation : Conserver le produit non entamé, de préférence, dans un endroit sec et frais. Pour toute information additionnelle avant utilisation, consulter la notice d-jointe.

Fabriqué en EU

Nutricia S.A., Chaussée Romaine 564C, 1853 Strombeek-Bever, Belgique.
Pour plus d'information: 070222307, medical.nutrition@nutricia.be - www.nutricia.be

NUTRICIA Nutrition Clinique, 150 Bd Victor Hugo, 93406 Saint-Ouen Cedex, France - www.nutricia.fr

A consommer de préférence avant: voir le dessous de la boîte.

IT Alimento dietetico destinato a fini medici speciali. Indicato per il regime alimentare della acidemia organica, ad esempio acidemia metilmalonica e acidemia propionica, nei lattanti. Miscela in polvere di aminoacidi, priva di isoleucina, metionina, treonina e valina, con carboidrati, vitamine, minerali ed oligoelementi.

Avvertenze importanti: Solo per uso enterale. Non somministrare per via parenterale. Utilizzare esclusivamente sotto controllo medico. Non indicato come unica fonte nutrizionale. Adatto a lattanti. Indicato solo per persone affette da acidemia organica.

Conservazione: Conservare il prodotto chiuso in luogo fresco e asciutto. Per ulteriori informazioni prima dell'uso vedere il foglietto illustrativo.

Prodotto in EU

Distribuito da: Nutricia Italia SpA, via C. Farini 41 - 20159 Milano.
Per informazioni: 800-822096 - www.nutricia.it
Notificato al Min.Sal. ai sensi del DPR 57 del 20/03/02

Da consumarsi preferibilmente entro: vedi base barattolo.

PT Alimento dietético destinado a fins medicinais específicas. Indicado para satisfação das necessidades nutricionais de lactentes com acidúria orgânica, como acidúria propionica e acidúria metilmalonica. Mistura em pó de aminoácidos, isenta de isoleucina, metionina, treonina e valina, que contém hidratos de carbono, vitaminas, minerais e oligoelementos.

Importante: Exclusivamente para uso entérico - não adequado para utilização por via parentérica. Deve ser consumido sob supervisão médica. Não adequado como única fonte de alimentação. Adequado para lactentes. Deve ser consumido unicamente por pacientes com acidúria orgânica.

Conservação: Conserve num local seco e fresco. Para obter mais informações antes de utilizar, ver folheto anexo.

Produzido na União Europeia

Distribuído em Portugal por: Nutricia Advanced Medical Nutrition - Unipessoal, Lda, Avenida D. João II nº41, 3º piso Torre Zen, 1990-084 Lisboa, Telef: 214 259 600. Fax: 214 184 619.
Linha verde: 800 206 739, www.nutricia.pt

Lote nº Consumir de preferência antes de: ver fundo da lata 500g e

TR Özel tıbbi amaçlı diyet gıda. Organik asidemili (metilmalonik asidemi ve propiyonik asidemi) bebeklerin diyet yönetiminde kullanılmak içindir. Karbonhidrat, vitaminler, mineraler ve eser elementler içerir. İzoleisin, metiyonin, treonin ve valin içermeyen amino asitlerin bir karışımıdır.

Önemli Uyarı: Sadece enteral kullanım içindir, parenteral kullanıma uygun değildir. Tıbbi gözetim altında kullanılmalıdır. Tek başına beslenme kaynağı olarak kullanıma uygun değildir. Bebeklerin kullanımı içindir. Sadece organik asidemisi olan bireyler tarafından kullanılmalıdır.

Kullanma talimatı: Açılmamış ürünü serin ve kuru bir yerde saklayın. Ürünü kullanımı ile ilgili daha fazla bilgi için ekteki kitapçığa bakın.

Üretici firma: SHS International Ltd, 100 Waverree Boulevard, Liverpool, L7 9PT, İngiltere

T.C. Sağlık Bakanlığının izniyle ithal edilmiştir.

Numül Gıda Ürünleri San. ve Tic. A.Ş. Yapı Kredi Plaza B Blok No:1B Kat:8-9 Cömert Sok. Levent Mah. Beşiktaş-İstanbul Tel:0212 385 26 00

Son kullanma tarihi: Kutunun altına bakın.

ZCSH902185_RE.ap/6/17/16 9:16 AM/PANTONE 268 C/PANTONE 3272 C/PANTONE 3242 C/PANTONE 2655 C/Keyline/

DSN
ARTWORK PREPRESS

DeSchutter Neroc nv
Blancfloerlaan 179a
2050 Antwerp
Belgium

Telephone: +32 3 222 38 00
E-mail: Info@ds-n.com

Job Name ZCSH902185_RE.ap
DSN Code ZCSH902185
Description 160073CM Milupa OS 1 Unfavoured 500G LABEL EN, DE, NL, FR, IT, PT, TR
Account SHS INTERNATIONAL LTD

Account Executive Mail
Pack Code 10277109
Previous Pack Code 10190937
Corporate Code 113600
Artwork Loop 2
Repro Loop 1
Packtype TIN
Printer DENNY BROS LTD
Material Code ***
KEY004 MEDIUM CAN MLL LABEL

Technical Plan
Unwind Direction ***
Printing Process Flexo
Date 6/17/16
Time 9:16 AM
Height (mm) +109.
Width (mm) +325.
Ink Coverage (%) 300%
Profile Number PR0001633
Proof Profile DENNY BROS LTD Raflatoc Cast Gloss RP51 CMYK E79 G250

First Barcode Number ***
2D Code Number ***
Barcode BWR (µm) 0,00

Check our website!

Check printed size by aligning a ruler along this ruler.
E.g.: When your ruler measures the printed ruler as 75 mm, this means that this document was printed on 75%.



DSN expects that this PDF will be checked completely regarding all text, lay-out, cutter, product code and barcode. If no correction is communicated about any of these items, DSN will consider this as being approved for further processing and ultimately printing. Due to limitations of digital proofing this PDF cannot be seen as a final printing result.

Questions? We are at your service.

This file was specifically produced for:



Separations

	PANTONE 268 C	Ink Surface: 9.7%
	PANTONE 3272 C	Ink Surface: 38.4%
	PANTONE 3242 C	Ink Surface: 4.1%
	PANTONE 2655 C	Ink Surface: 0.1%
	Keyline	Ink Surface: 0.9%
	Ink Surface: %	
	Ink Surface: %	
	Ink Surface: %	
	Ink Surface: %	
	Ink Surface: %	
	Ink Surface: %	
	Ink Surface: %	
	Ink Surface: %	



