RWANDA FDA
Rwanda Food and Drugs Authority
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Kigali, 29/01/2020
Ref N° 137 /RwandaFDA/2020

District Pharmacy (All)
District Hospital (All)
Referral Hospital (All)
Wholesale Pharmacy (All)
Retail Pharmacies (All)
Private clinics/ (All)

Title:Recall for some batches of Trimebutine (Debridat® 4.8mg/ml granules for oral suspension, 125 ml and 2 Debridat® 24mg/5ml granules for oral suspension, 250 ml)

Reference made to the law N° 003/2018 of 09/02/2018 establishing Rwanda FDA, especially in its article 8, paragraph 13, the Authority is mandated to regulate compliance with quality standards relating to the manufacture, storage, sale, distribution, use, import and export, labels, packages and raw materials used in the manufacture of products regulated under this Law also in its article 8 paragraph 13 the Authority is mandated to disseminate information on quality and safety of products regulated under this Law to health professionals and to other concerned persons;

It is in this regards that Rwanda FDA has received a notification of quality issue from the marketing authorization holder (Pfizer) where some batches of debridat granules for oral suspension were found with potential foreign materials in the product. However, as a precautionary measure, the company is voluntarily recalling the products from the market. Rwanda FDA regrets to notify that the following batches were affected:

Description	Batch Number	Exp. Date	Manufacturer	Marketing Authorization Holder
Debridat®24mg/5ml granules for oral suspension, 250 ml	3814	06/2020	FARMEA 10, rue Bouche Thomas Zac SUD d'ORGEMONT 49000 Angers	Pfizer Holding France
	3815	06/2020		
	3816	06/2020		
	3817	06/2020		
	3818	06/2020		

	3819	06/2020		
	3820	06/2020		
	3851	10/2020		
	3852	10/2020		
	3853	10/2020		
	3867	02/2021		
Debridat®4.8mg/ml granules for oral suspension, 125 ml	3856	11/2020	FARMEA 10, rue Bouche Thomas Zac SUD d'ORGEMONT 49000 Angers	Pfizer Holding France
	3857	11/2020		
	3858	11/2020		
	3859	12/2020		
	3860	12/2020		

Action to be taken

Rwanda Food and Drug Authority instructs all importers, wholesale pharmacies, District Pharmacies, retailers pharmacies, Public and Private Health Facilities to stop the distribution and dispensing of the above incriminated batches of debridat granules for oral suspension and return them to suppliers for suitable management.

The importers and suppliers of incriminated debridat granules for oral suspension are requested to report to Rwanda FDA within 10 working days the quantities imported per product, quantities distributed, quantities returned and final stock on hand.

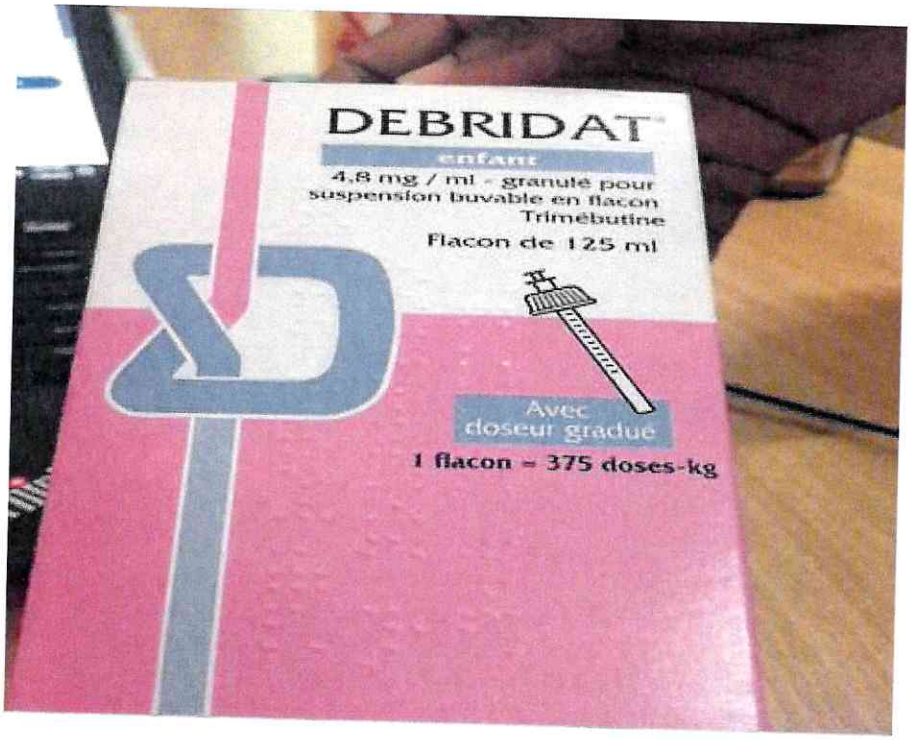
Sincerely,

RWANDA FOOD AND DRUGS AUTHORITY • RWANDA FDA

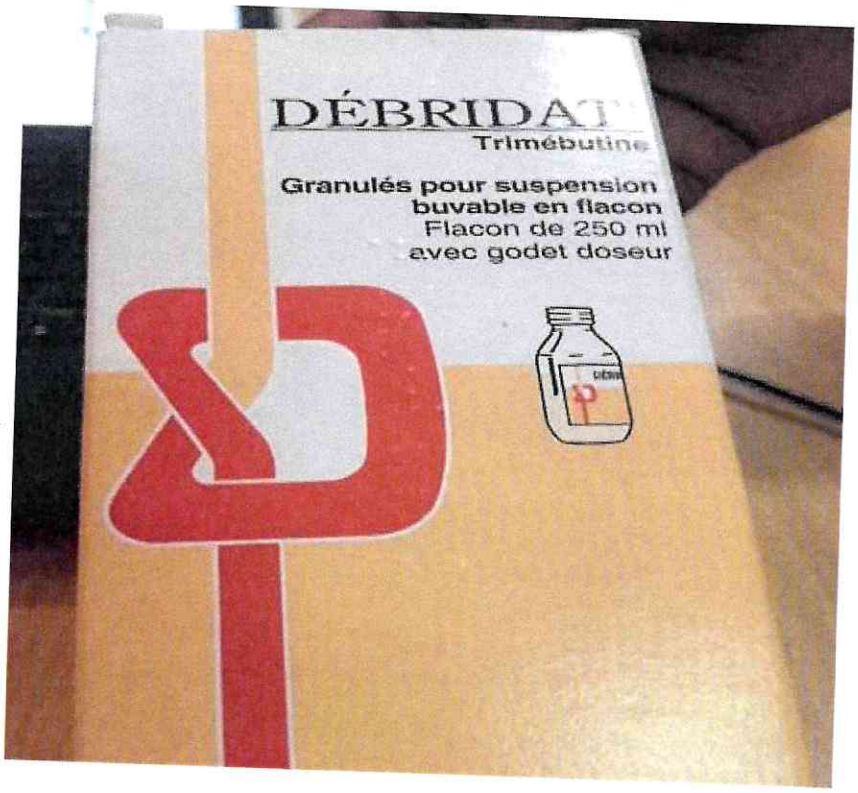
Dr. Charles KARANGWA
Ag. Director General

CC:

- **Hon. Minister of Health**
- **Hon. Minister of state in Charge of Primary Health care**


DEBRIDAT
enfant
4,8 mg / ml - granulé pour suspension buvable en flacon
Trimébutine
Flacon de 125 ml
Avec doseur gradué
1 flacon = 375 doses-kg


DEBRIDAT
enfant
4,8 mg / ml - granulé pour suspension buvable en flacon
Trimébutine


DÉBRIDAT
Trimébutine
Granulés pour suspension buvable en flacon
Flacon de 250 ml
avec godet doseur


DÉBRIDAT
trimébutine
Granulés pour suspension buvable
Flacon de 250 ml
avec godet doseur.
Composition en substance active :
Trimébutine 0,7870 g
Pour 100 g.
Excipients à effet notoire: saccharose, jaune orangé S (E110).
Mode et voie d'administration :
Voie orale. Lire la notice avant utilisation.
Flacon de 250 ml avec godet doseur.
Suspension à reconstituer.
Agiter avant chaque utilisation.
Après reconstitution, la suspension ne doit pas être conservée plus de 4 semaines.
Liste II - Uniquement sur ordonnance
Tenir hors de la vue et de la portée des enfants.
Médicament autorisé N° : 34009 302 825 2 6