
Urgent Field Safety Notice

AbbVie PEG 20FR Tube

Date: Wednesday, 09 November 2016

Dear Customer / Health Care Professional

This letter is to advise you of a disconnection issue regarding the above referenced medical device (AbbVie PEG 20FR Tube). This product is used for the administration of the medicinal product Duodopa™ (levodopa carbidopa intestinal gel) / Duopa™ (carbidopa and levodopa enteral suspension) for the treatment of advanced Parkinson's disease.

AFFECTED PRODUCT	AbbVie PEG 20FR Tube. The AbbVie PEG 20FR Tube is used for the administration of Duodopa/Duopa and is intended to provide long-term enteral access for administration of medication to the small intestine when used in conjunction with the AbbVie J (intestinal) Tube. As needed, enteral nutrition may be administered directly to the stomach in parallel with medication delivery to the intestine.
PROBLEM DESCRIPTION	AbbVie has detected an increase in the number of reports of disconnection of the external Y-Connector from the AbbVie 20FR PEG Tube where the connection cannot easily be re-established using the existing Y-Connector or a replacement Y-Connector. This issue has been observed in a number of AbbVie PEG 20FR Tubes with geographic variability in reports. These disconnections have occurred between 1 and 12 months post insertion. In some instances, this issue may result in the need for medical / surgical intervention to replace the PEG 20FR Tube.
HAZARD INVOLVED	The reported disconnection events have not been associated with any reports of serious injury related. A Health Hazard Assessment determined the potential safety risk to be low. There is a remote possibility of significant adverse health consequences with the use or exposure to the impacted product.

HOW TO IDENTIFY AFFECTED PRODUCT

The product is identified as the AbbVie PEG 20FR labelled as PEG Kit 20FR.

A description of various reference numbers per market is provided below

Reference Number (REF)	Name on Label	Market
62945-001	AbbVie™ PEG PEG Kit 20FR	Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, Turkey
62945-002	AbbVie™ PEG PEG Kit 20FR	Albania, Australia, Bulgaria, Croatia, Czech Republic, Hungary, Israel, Japan, Romania, Saudi Arabia, Slovakia, Slovenia, Thailand
62912-002	AbbVie™ PEG PEG Kit 20FR	United Kingdom
62912-001	AbbVie™ PEG PEG Kit 20FR	United States
62945-A89	AbbVie™ PEG PEG Kit 20FR	Australia

The following batch numbers are currently in the market place:

Country	Lots Shipped
Austria	32085235, 32282264, 32344205, 32475415
Ireland	32085235, 32475415
Belgium	32041156, 32224175, 32282264, 32344205, 32475415
Italy	32085235, 32224175, 32344205, 32475415
Switzerland	32085235
Greece	32282264
France	32041156, 32085235, 32224175, 32344205, 32475415
Netherlands	32041156, 32183256, 32344205
United States	32025245, 32085235, 32265215, 32282274, 32335206, 32455234
Sweden	32183256, 32224175, 32475415
Turkey	32224175, 32282264, 32282274
Finland	32041156, 32085235, 32224175, 32282264
Germany	32041156, 32085235, 32085245, 32183256, 32224175, 32282264, 32282274, 32344205, 32455234, 32475415
Spain	32085235, 32224175, 32282264
Bulgaria	32344225
Canada	32282264
Czech	32085245, 32344225

	Republic	
	Denmark	32041156, 32211316, 32224175, 32344205
	Estonia	32085235, 32282264
	Japan	32085245, 32224175, 32282274, 32344205, 32344225, 32475415
	Norway	32041156, 32085235, 32224175, 32282264
	Puerto Rico	32025245, 32265215
	Romania	32085235, 32224175, 32282274, 32344225
	Russia	32282264, 32344205
	Slovakia	32085245, 32282274, 32344225

ACTION TO BE TAKEN BY CUSTOMER / USER

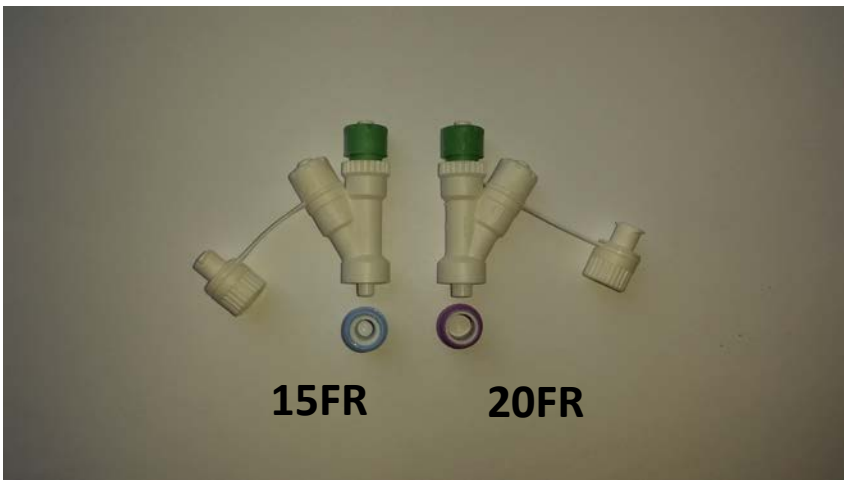
For patients currently using the AbbVie PEG 20FR Tube, please continue to monitor the performance of the Tube. There is no need to replace the AbbVie PEG 20FR Tube if it is functioning as expected and maintaining a viable connection with the Y-Connector.

When establishing a connection between AbbVie PEG 20FR Tube with the 20FR Y-connector, always refer to the AbbVie PEG 20FR Tube Instructions for Use. As stated in the instructions for use, please note the following:

1. Ensure that the set-up process clearly follows the sequence of events as described in the instructions for use.

2. Ensure that the AbbVie PEG 20FR tube is connected to the corresponding 20 Y-connector (*see photograph below which shows the difference between the 15FR and 20FR connection diameter*).

3. Do not use alcohol containing products with the AbbVie PEG 20 FR tube as they may result in damage to the tube.



Health Care Professionals should determine the appropriate PEG product based on the consideration of this disconnection issue and the clinical needs of the patient.

AbbVie PEG 15FR Tubes continue to be available for medically appropriate new patients placed on Duodopa/Duopa and for replacements.

For patients requiring enteral feeding (via PEG 20FR Tube), AbbVie PEG 20FR may continue to be used.

There may be alternative options available. AbbVie cannot make specific

	recommendations for alternative tubing and has no data supporting compatibility with Duodopa. Please contact AbbVie at 01 428 7934 with any questions regarding this issue, or regarding the supply of AbbVie PEG 20FR tubes. Health Care Professionals are requested to report any disconnection events to AbbVie, including details of the tubing lot number (both PEG Tube and Y-connector lot number) and a clear history of the use/duration of treatment with the AbbVie PEG 20FR Tube. In cases where the tubing is replaced, the AbbVie PEG 20FR and Y-connector samples should be returned to AbbVie for examination.
ACTIONS PLANNED BY ABBVIE	AbbVie is taking this issue very seriously and continuing to investigate it to determine the cause and provide appropriate solutions.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact AbbVie on 01 428 7934.

This notice has been reported to the appropriate Regulatory Agencies in the impacted countries.

AbbVie apologises for any inconvenience caused by this issue.

Cormac Dalton, PhD
Director Compliance, Supply Chain & Commercial Quality

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