

Brignais, le 04/07/2019

Predmet / Object :

Opozorilni list / Field Safety Notice

Znamka end-ball, referenčni ENDT110 / Trade name end-ball, reference ENDT110

Vrsto ukrepa / Type of action :

Opozorilni list za distributerje in končne uporabnike /

Field safety notice for distributors and end-users

1- Zadevna naprava / Affected device

Vse številke intragastričnih balonov end-ball, ENDT110.

All numbers of batches of the end-ball intra-gastric balloon, ENDT110.

2- Opis problema / Description of the problem :

Podjetje izdelava opozorilno kartico:

- Varnostno opozorilo, ki ga je kanadski pristojni organ za zdravje Kanade izdal 17. aprila 2019, o možnih tveganjih, povezanih z uporabo intragastričnih balonov kot zdravilo za debelost:

- o Perforacija želodca in požiralnika,
- o akutni pankreatitis
- o Spontana hiperinflacija

- Po primeru akutnega pankreatitisa, o katerem je bilo poročano v podjetju ENDALIS maja 2019 (skrb za materijo, ki jo je ENDALIS izdal pristojnim organom)

V uporabniškem priročniku niso bili omenjeni zapleti akutnega pankreatitisa in spontana hiperinflacija balona end-ball, ENDT110.

The ENDALIS company initiates a field safety notice following:

- The safety alert issued by the Canadian Competent Authority, Health Canada, April 17th, 2019, on the potential risks, associated with the use of intragastric balloons in weight loss therapy, of

- o Gastric and esophageal perforation,*
- o Acute pancreatitis,*
- o Spontaneous balloon overinflation.*

- Following a case of acute pancreatitis reported to the company ENDALIS in May 2019. (Vigilant incident issued by Endalis to the Competent Authorities)

The complications of acute pancreatitis and spontaneous balloon overinflation were not mentioned in the end-ball instructions, ENDT110.

3- Ukrepi, ki jih sprejme proizvajalec / Actions indertake by the manufacturer

Akutni pankreatitis in spontani hiperinflacijski zapleti bodo dodani v poglavju 9 navodil za uporabo end-ball ENDT110.

Pred: Poglavje "Zapleti"	Po: Poglavje 9: Zapleti
<p>Naveden je bil naslednji zaplet:</p> <ul style="list-style-type: none"> - Zapleti, povezani z namestitvijo ali odvzgom balona - Mehanski zapleti zaradi balona <ul style="list-style-type: none"> • Opisane so bile ulceracije stene želodca, ki lahko povzročijo perforacijo (težnost balona napolnjena s 100% tekočino), ki zahteva nujno kirurško intervencijo s ključnim tveganjem. • v primeru migracije, ki jo opazimo v primeru nezadostno napolnjenega ali delno izpuhanega balona, so možne ovire prebavnega trakta; lahko je obstrukcija želodca v primeru zagodenja balona v želodčni antrum ali črevesno obstrukcijo, ki včasih zahteva operacijo. <p>Tveganje teh zapletov se močno poveča, če se ne upošteva najdaljše možno obdobje šestih mesecev.</p> <ul style="list-style-type: none"> - Funkcionalni zaplet (neželeni učinek) \ t - Presnovni zapleti - Šah 	<p>Dodajanje dveh novih zapletov:</p> <ul style="list-style-type: none"> - Zapleti, povezani z namestitvijo ali odvzgom balona - Mehanski zapleti zaradi balona <ul style="list-style-type: none"> • Razjede na steni želodca lahko povzročijo perforacijo zaradi teže balona, napolnjenega s tekočino, ki zahteva nujno kirurško intervencijo s ključnim tveganjem. • Možne so ovire prebavnega trakta v primeru migracije, ki jo opazimo v primeru nezadostno napolnjenega ali delno izpuhanega balona; lahko je obstrukcija želodca v primeru zagodenja balona v želodčni antrum ali črevesno obstrukcijo, ki včasih zahteva operacijo. <p>Tveganje teh zapletov se močno poveča, če se ne upošteva najdaljše možno obdobje šestih mesecev.</p> <ul style="list-style-type: none"> • V literaturi je opisana nevarnost spontane hiperinflacije bučke zaradi proizvodnje plina v bučki. • Akutni pankreatitis je mogoč zaradi mehanskega pritiska balona na trebušno slinavko skozi želodčno steno. <ul style="list-style-type: none"> - Funkcionalni zaplet (neželeni učinek) \ t - Presnovni zapleti - Šah

The complications of acute pancreatitis and spontaneous balloon overinflation will be added in chapter 9 of the instructions for use (end-ball, ENDT110).

Before : Chapter « Complications »	After : Chapter 9 : « Complications »
<p>The following complications were mentioned:</p> <ul style="list-style-type: none"> - Complications linked to the insertion or extraction of the balloon - Mechanical complications due to the balloon: <ul style="list-style-type: none"> • Ulceration of the gastric wall which could result in perforation has been described (heaviness of the balloon filled with 100% liquid) necessitating an urgent surgical operation with risk to life. 	<p>Addition of 2 new complications :</p> <ul style="list-style-type: none"> - Complications linked to the insertion or extraction of the balloon - Complications mécaniques dues au ballon <ul style="list-style-type: none"> • Ulcerations of the gastric wall can lead to perforation due to the heaviness of the balloon filled with fluid, necessitating an urgent surgical operation with risk to life. • Digestive tract obstructions are possible where there is migration, which is seen if

<ul style="list-style-type: none"> • <i>Digestive tract obstructions are possible where there is migration, which is seen if the balloon is not sufficiently filled or is partially deflated. It can be a gastric obstruction if the balloon becomes impacted in the gastric antrum or an intestinal obstruction which sometimes requires a surgical operation.</i> <p><i>The risk of these complications is greatly increased if the maximum duration of six months for the implantation of the intra-gastric balloon is not respected.</i></p> <ul style="list-style-type: none"> - Functional complications (side effects) - Metabolic complications - Failures 	<p><i>the balloon is not sufficiently filled or is partially deflated. It can be a gastric obstruction if the balloon becomes impacted in the gastric antrum or an intestinal obstruction which sometimes requires a surgical operation.</i></p> <p><i>The risk of these complications is greatly increased if the maximum duration of six months for the implantation of the intra-gastric balloon is not respected.</i></p> <ul style="list-style-type: none"> • A risk of spontaneous balloon overinflation due to gas production in the balloon has been described in the literature. • Acute pancreatitis is possible due to mechanical pressure exerted by the balloon on the pancreas through the gastric wall. - Functional complications (side effects) - Metabolic complications - Failures
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4- Dejanja za stranke (uporabnike)/ Advise on action to be taken by the user:

- Distributerji morajo navodila za uporabo prebrati in jih posredovati zdravstvenim delavcem, ki uporabljajo intragastrični balon.
- Zdravstveni delavci morajo prebrati navodila za uporabo.
- Zdravstveni delavci morajo bolnike nato obvestiti o morebitnih zapletih, navedenih v navodilih za uporabo.
- *Distributors must read the enclosed instructions for use carefully and communicate the instructions for use to the healthcare professionals.*
- *The healthcare professionals should read the instructions for use carefully.*
- *The healthcare professionals should then warn patients of possible complications listed in the instructions for use.*

5- Sporočanje tega opozorilnega lista / Field Safety Notice (FSN):

To izjavo o omejitvi odgovornosti morate deliti z vsemi v vaši organizaciji, ki morajo vedeti za to, končnim uporabnikom ali kateri koli organizaciji (zdravstvenim domovom), za katere izdelke ste lahko prenesli. (Če je potrebno)

Ta obrazec pošljite drugim organizacijam, za katere ima ta učinek učinek. (Če je potrebno)

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (If appropriate)

Please transfer this notice to other organisations on which this action has an impact. (If appropriate)

6- 6- Kontakt osebe, ki se nanaša: / Contact reference person:

Če imate kakršna koli vprašanja, nam pišite na:

If you have any questions, please contact us:

Država /Country	Naslov/Address	kontakt/Contact	Telefon /Phone	E-mail
France	ENDALIS 1 Allée des Tilleuls 69530 Brignais	Pierre-André DENIS Marie-Ange BOILLETOT	(33) 435575700	padenis@endalis.com qualite@endalis.com
Slovenia	PRO-GEM d.o.o Cesta na Brdo 85, SLO 100 LJUBLJANA	Majda Vrbinc	014233738 , +38614233738	majda.vrbinc@pro-gem.si

ENDALIS potrjuje, da sta bila ANSM in JAZMP obveščena o tem opozorilnem listu. *The ENDALIS company confirms that ANSM and JAZMP were informed of the FSN*

Podpis

Pierre-André DENIS

Potrdilo o prejemu / Acknowledgment of receipt

Podpisani potrjuje, da je prejel opozorilo z dne 4. julija 2019 in da bo ustrezno ukrepal.

The undersigned confirms that he/she has received the FSN of 4 July 2019 and he/she will act accordingly.

Država / Country:

Ime / Name:

Datum in podpis / Date and signature :