Medifactia®

INSTRUCTION FOR USE OF TRANSIT-PELLETS™ RADIOPAQUE MARKERS

Summary Product Information

Seven (7) capsules (size -00-) per package intended for single patient use. Five (5) of these capsules contain ten (10) ring-formed radiopaque markers and two (2) of the capsules contain five (5) tube-formed radiopaque markers. To be dispensed only by physician to patients for oral intake.

Intended Use

The Transit-Pellets device is intended to be used for evaluation of colonic transit time in patients with chronic constipation and used to aid in differentiating slow and normal transit constipation. Both total colonic transit time (CTT measured as the substitute oro-anal transit time, OATT) and segmental transit dysfunction can be evaluated with the device. In addition, the measurement may be done in patients with chronic diarrhoea to determine if the dysfunction is linked to abnormally rapid or to normal transit rate.

User/Target Population

The device is prescribed by a physician for the patient to administer the device at home. The device is for a chronic or severe state, where the initial treatment has not resolved the abdominal discomfort, such as:

- In patients with chronic constipation and used to aid in differentiating slow and normal transit constipation
- In patients with chronic diarrhoea to determine if the dysfunction is linked to abnormally rapid or to normal transit rate
- In patients with irritable bowel syndrome (IBS) with troublesome constipation or troublesome diarrhoea

Contraindication

Patients who are hypersensitive to Hypromellose methylcellulose E464, Elastosil® R 401/60 Silicone Rubber, Barium Sulphate $BaSO_4$ powder EMPROVE

Warnings

- Safety and effectiveness in children (<18 years of age) have not been established
- Determine whether the patient is at risk of aspiration or choking and what exactly can be swallowed with respect to texture
- Not for use in pregnant women due to the radiation issue

Precautions

- Instruct the patient to avoid laxatives, such as bulk-forming fibers, suppositories and saline enemas for seven days
- Use of medications known to influence gastrointestinal motility (for example prokinetics, opioids, etc.) should be considered when interpreting test results
- Careful instruction to the patient for correct timing of capsule ingestion is important in order to obtain a representative result

Clinical Studies

Please see: https://medifactia.com/research/

Declaration of Contents

Capsules: Hypromellose methylcellulose E464
Markers: Elastosil® R 401/60 Silicone Rubber (78%), Barium Sulphate $BaSO_4$ powder EMPROVE (22%)

Directions for Use

Direct the patient to swallow Transit-Pellets™ capsules by mouth with for example water for six consecutive days. Alternative methods for those who cannot swallow the capsule include opening the capsule, and emptying the contents into soft food (applesauce, yogurt, or similar food). After swallowing the capsule and its contents, instruct the patient to drink some more to ensure the capsule and its contents has been swallowed completely. Instruct the patient to not chew on the capsules or markers.

One (1) capsule is to be swallowed in the morning day 1 thru day 5. On day six one (1) capsule is to be swallowed in the morning, 24 hours prior to X-ray, and one (1) capsule is to be swallowed in the evening, 12 hours prior to X-ray (Table 1). The capsules dissolve in the gut and will release the markers and the markers will pass out with faeces. The numbers 6:1 and 6:2, printed on the back of the blister, correspond to the morning dose on day six and the evening dose on day six. It is important that the markers are taken every day exactly as prescribed. The interval between first marker intake and the X-ray must be six days (approx. 144 hours). By dividing the marker dose on day six the whole range of transit times - slow, normal and rapid transit can be measured from the radiograph.

Table 1. Schedule for marker intake

Day	1	2	3	4	5	6:1	6:2	7
Time prior to X-ray	*6 days*	*5 days*	*4 days*	*3 days*	*2 days*	*24 hrs.*	*12 hrs.*	
Ring-formed markers	10	10	10	10	10			
Tube-formed markers						5	5	
Abdominal X-ray								X

Arrange a plain abdominal X-ray on day seven to determine the location and extent of elimination of the radiopaque markers. The distribution of markers in the various colonic segments can provide information about the type of delay (Table 2 and 3). Colonic transit time is calculated as the mean oro-anal transit time (OATT, mouth-to-anus) for the daily marker doses swallowed. With a daily dose of ten (10) markers, the transit time in days is M divided by 10, i.e., the number of markers counted from the X-ray film (M) divided by the daily dose. A different shape of the markers is used on day six to assist in localization of caecum and the division of the day 6-dose into a morning and an evening dose will enhance precision in measuring rapid transit.

With ten (10) markers per day, each marker is equivalent to 0.1 days or 2.4 hours. (i.e., 2.4 hrs. per marker). The formula Mx2.4 can be used on both total and segmental transit time for clinics that prefer a result in hours.

Reading the Results

Both total transit and segmental transit dysfunction in the colon can be evaluated. A numerical transit value can be given if the number of retained markers is in the range 3-55 markers. Thus, at least half a

daily dose should be excreted and at least half of the evening dose on day six must be retained. If the number of retained markers is only 0-2, the transit time is less than 0.3 days. If 56-60 markers are retained, the transit time is more than 5.5 days (an equilibrium has not been reached).

Table 2. Colonic transit time (OATT); reference values

Women			Men		
No. of markers	*Days*	*Type of transit*	*No. of markers*	*Days*	*Type of transit*
0-5 markers	<0.6 days	Rapid transit	0-4 markers	<0.5 days	Rapid transit
6-40 markers	0.6-4.0 days	Normal transit	5-22 markers	0.5-2.2 days	Normal transit
41-50 markers	4.1-5.0 days	Moderately delayed transit	23-40 markers	2.3-4.0 days	Moderately delayed transit
51-60 markers	>5.0 days	Clearly delayed transit	41-60 markers	>4.0 days	Clearly delayed transit

Normal transit time corresponds to the range from percentile 5 to percentile 95 in the control material. Reference values based on 199 subjects: 1) Abrahamsson et al., Scand J Gastroenterol 1988 Suppl 152:72-80; 2) Sadik et al., Scand J Gastroenterol 2003, 38:36-42; 3) Törnblom et al., data on file, Gastrointest Lab, Sahlgrenska University Hospital.

Table 3. Segmental transit time; upper reference values

	Caecum-Ascending colon	*Transverse colon*	*Descending colon*	*Sigmoid colon-rectum*	*Total*
Women	1.3	0.7	2.3	1.3	4.0
Men	1.0	0.5	1.2	1.3	2.2

Segmental transit time: Abrahamsson et al., Scand J Gastroenterol 1988 Suppl 152:72-80. Percentile 95 calculated *per segment* in healthy subjects.

LOT Batch code

Use-by date

Do not re-use

Consult instructions for use

MD Medical device

Legal manufacturer

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