INSTRUCTION FOR USE OF TRANSIT-PELLETS™ RADIOPAQUE MARKERS

Summary product information

Seven (7) capsules 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.

Indications for Use

For evaluation of colonic transit in patients with chronic constipation and used to aid in differentiating slow and normal constipation.

Applications for transit measurement

- When a patient with constipation does not respond to treatment
- Repeated measurement for documentation of effects of treatment
- In cases of chronic diarrhea, when an objective measurement of rapid transit is wanted
- Suspicion of constipation-induced diarrhea: the test will show a slow transit despite the patient's report of loose stools

Contraindications

Patients who are hypersensitive to Hypromellose methylcellulose E464, Elastosil® R401/60 Silicone Rubber, Barium Sulphate BaSO4 powder EMPROVE

Warnings

- Safety and effectiveness in children (<18 years of age) have not been established
- Not for use in pregnant women due to the radiation issue

Precautions

- Instruct the patient to avoid laxatives, enemas or suppositories 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® R401/60 Silicone Rubber (78%), Barium Sulphate BaSO4 powder EMPROVE (22%)

Directions for Use

Direct the patient to swallow Transit-Pellets™ capsules by mouth with water for six consecutive days. 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. By dividing the marker dose on day six the whole range of transit times (slow, normal, rapid) transit can be measured from the radiograph.

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. 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 (Table 1 and 2). A different shape of the markers is used on day six to assist in localization of cecum and the division of the day 6-dose into a morning and an evening dose will enhance precision in measuring rapid transit.

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 1. 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 Univ. Hospital.

Table 2. Segmental transit time; upper reference values

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

LOT Batch

Use before

Manufacture

Read usage instructions

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