

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.



Instruction for Use

For evaluation of colonic transit in adult and pediatric patients (at least 2 years old) with chronic constipation and used to aid in differentiating slow and normal transit 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

Pediatric Instructions

- Assurance that pediatric patients can swallow the capsule and its contents comfortably is required
- 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)

Contraindications

- Patients who are hypersensitive to Hypromellose methylcellulose E464, Elastasil® R 401/60 Silicone Rubber, Barium Sulphate BaSO₄ powder EMPROVE
- Patients with swallowing difficulties

Warnings

- 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, enemas or 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 BaSO₄ 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). By dividing the marker dose on day six the whole range of transit times (slow, normal, 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
<i>Time prior to X-ray</i>	<i>6 days</i>	<i>5 days</i>	<i>4 days</i>	<i>3 days</i>	<i>2 days</i>	<i>24 hrs.</i>	<i>12 hrs.</i>	
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. 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 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 Result

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). For further information, please see www.medifactia.com

Colonic Transit Time (CTT/OATT); Reference Values

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.


Segmental Transit Time; Upper Reference Values


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

R_x Only Caution: Federal law restricts this device to sale by or on order of a licensed physician

 Batch code

 Use-by date

 Do not re-use

 Consult instructions for use

 Medical device

 Legal manufacturer

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