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 adult 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 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. 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
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 (OATT); reference values

Segmental transit time; upper reference values

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

Batch

Use before

Manufacture

Read usage instruction

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