in labor induction
Unique combination of efficacy
safety and patient satisfaction
Multiple mode of action¹ mimics physiological processes of the labor

- Mechanical: Controlled pressure on the cervical wall dilates the cervix
- Biophysical: Partial reversible osmotic dehydration softens the tissue
- Physiological: Promotion of endogenous prostaglandins release causing collagen degradation and tissue restructuring

Dilapan-S® doesn’t contain any pharmacologically active substance, which could be released during its use.

Efficacy and safety confirmed by

- International observational e-registry on the use of Dilapan-S® osmotic dilator for cervical ripening prior to labor induction (ongoing)²,³
  - 11 study sites from 7 countries participate in the project to collect induction of labor clinical data
  - Data from 6 centers / 214 patients included in the 1st interim analysis in Q4/2015
- Prospective clinical study comparing Dilapan-S® with PGE2 gel and Estradiol gel⁴
  - 247 patients randomized, 82 treated by Dilapan-S®
- Prospective, observational, multicentre data collection on the use of osmotic dilator Dilapan-S® in labor pre-induction in females with/without Caesarean section in medical history⁵-⁸
  - 6 study sites collected data from 96 patients, incl. women with previous Caesarean section
- Prospective observational study evaluating Dilapan-S® efficacy and safety⁹
  - 92 patients
- Retrospective study evaluating efficacy and safety of Dilapan-S® in labor pre-induction¹⁰,¹¹
  - 68 patients, incl. women with previous Caesarean section

General recommendation for the treatment regimen:

<table>
<thead>
<tr>
<th>Cervical ripening</th>
<th>Labor induction (promotion of uterine contraction)</th>
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<tbody>
<tr>
<td>3 - 4 pieces of Dilapan-S®</td>
<td>4 x 55 mm for 12 -15 hours*</td>
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* Number of pieces can differ depends on initial Bishop score.
** Artificial rupture of membranes can be proceeded if beneficial and in line with local clinical protocol.
*** Dilapan-S® ripens the cervix independently on uterine contractions. After the cervical ripening, uterotonic such as oxytocin is recommended to promote adequate uterine contractions, if cervical ripening does not develop into spontaneous vaginal birth.
Dilapan-S®

Efficacy
- Significant Bishop score increase 2–11 and vaginal delivery rate up to 80%2,3,4
- Spontaneous vaginal delivery with no pharmacological intervention up to 20%2,3,5–8,11
- Suitable for VBAC2,3,6,10

Safety2–11
- No hyperstimulation or fetal pathology during cervical ripening
- No infectious complications related to the use of Dilapan-S®
- No limitation related to mother’s gestational age and/or comorbidities

Patients’ satisfaction
- Low rate of uterine contractions during cervical ripening2,3,5–8,10,11
- Up to 90% of women can relax or sleep during cervical ripening5–8
- Minimising of vaginal examination during cervical ripening

Cost-effectiveness
- Potential prevention of C. sections in high-risk groups of patients2,3,5–8,10,11
- Out-patient regimen (home cervical ripening) for low-risk groups of patients2,3,4
- Saving time of health care professionals thanks to one-time application and no need of continuous CTG monitoring12

Unique combination of efficacy, safety and patient satisfaction
- For clinicians helps to minimize safety risks while maintaining high efficiency2–11
- For mothers ensures gentle and predictable cervical ripening and promotes natural vaginal delivery2–11
- For health care providers offers reduction of overall healthcare cost2,3,4

Dilapan-S®
Gentle. Predictable.
- Fast acting hygroscopic cervical dilator made of patented AQUACRYL hydrogel specifically developed for obstetrics and gynaecology.¹
- Approved in more than 40 countries worldwide⁴ for labor induction, including USA (510(k), Class II) and EU (CE mark, Class IIa).
- Manufactured at an ISO 13485 certified facility. Sterilized by gamma irradiation.

Sources/References:
6. Huban L et al.: Effectiveness and safety of the osmotic dilator Dilapan-S® for cervical ripening in women with/without C-section in medical history. Poster presentation. XXXV European Congress of Perinatal Medicine, June 104, Florence, Italy
7. Zahumensky J et al.: The impact of the number of pieces of osmotic dilator Dilapan-S® used for cervical ripening on the course and outcome of labor. Poster presentation. 13th World Congress in Fetal Medicine, June-July 2014, Nice, France
8. Vuk R et al.: Efficacy and safety of the osmotic dilator Dilapan-S® for cervical ripening in women with/without C-section. Poster presentation. 13th World Congress in Fetal Medicine, June-July 2014, Nice, France
9. Simakova O et al.: Effect of hygroscopic dilator Dilapan-S® on cervical ripening prior to induction of labor. Poster presentation. 30th European Congress of Perinatal Medicine, June 104, Florence, Italy
10. Huban L et al.: Evaluation of the effectiveness and safety of Dilapan-S® for cervical ripening in labor preinduction. Oral presentation. 13th World Congress of Perinatal Medicine, June 2013, Moscow, Russia
11. Huban L et al.: What is the position of mechanical preinduction cervical ripening in modern obstetrics? Oral poster presentation. 15th World Congress, June 2013, Liverpool, UK
12. Data on file
13. Dilapan-S® Instruction for use

⁴The date of January 2016 it is 44 countries. Worldwide registrations including pseudomar notification, no objection letters and other types of governmental approvals and EEA, incl. Switzerland and Turkey.