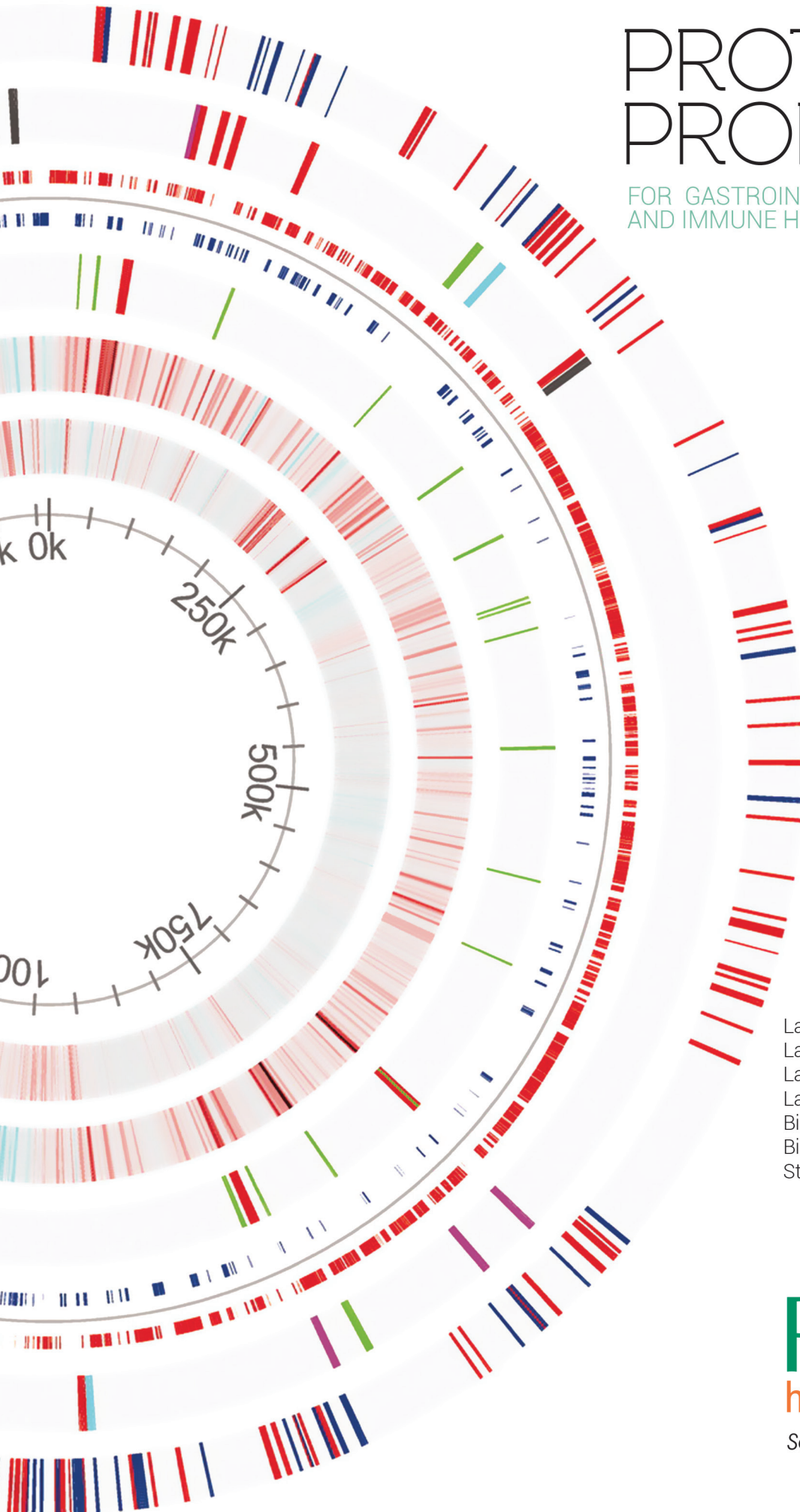


Strain specific synbiotics,
trusted in more than 60
countries around the world.

PROTEXIN PROBIOTICS

FOR GASTROINTESTINAL
AND IMMUNE HEALTH



Lactobacillus casei **PXN 37**
Lactobacillus rhamnosus **PXN 54**
Lactobacillus acidophilus **PXN 35**
Lactobacillus bulgaricus **PXN 39**
Bifidobacterium breve **PXN 25**
Bifidobacterium longum **PXN 30**
Streptococcus thermophilus **PXN 66**

Protexin[®]
health care 

Science and nature in balance



Protexin is a high grade supplement to deliver probiotics in doses of 2×10^9 to 2×10^9 to re-balance microbiome dysbiosis in the gut, affected by illness, environment, genetics and lifestyle.

The high manufacturing quality of Protexin ensures increased efficacy to allow greatest colonisation of the gut.

During manufacturing, specialist microencapsulation and lyophilisation (freeze-drying) processes ensure bacterial integrity. High acid resistance ensures effective passage through the stomach.

Protexin is multi-strain and multi-species. It is a synbiotic, containing prebiotics in the form of fructooligosaccharide.

Protexin does not need refrigeration and its stability is guaranteed for two years at room temperature.

Protexin was the first probiotic to be registered in Iran and has probably the largest body of evidence of all probiotics in Iran, having been tested by leading physicians and specialists in the country.

WHAT IS A GOOD PROBIOTIC

“Not all probiotics are the same.”

International Scientific Association for Probiotics and Prebiotics (ISAPP);
American Gastroenterology Association.



Streptococcus thermophilus

WHAT IS THE STRAIN?

Strains are specific to the product. No other product has the same strains as Protexin. Finding and testing strong strains takes years of research and not every manufacturer has access to the strongest strains.

A probiotic is defined by its genus (e.g. Lactobacillus), species (e.g. rhamnosus) and strain designation (e.g. PXN54). According to the World Health Organization, manufacturers should state the name of the strain on their packaging – What probiotic is inside? (ISAPP)



Lactobacillus acidophilus

Strains must have high antimicrobial properties, be resistant to stomach acid and also be able to adhere effectively to epithelial cells – have high hydrophobicity.

MANUFACTURING QUALITY

Today, international standards for manufacturing high quality supplements require GMP standards. The manufacture of efficacious probiotics involves complex advanced techniques and experience, built on strong research and maintained with continuous quality control.

If the highest standards are not maintained, a product can deteriorate very quickly and its efficacy can fall to zero.



Lactobacillus bulgaricus

That is why it is important to use products which have shown consistently high quality over a long period of time.

PROTEXIN USAGE

DIARRHEA

In hospital and doctors prescriptions Protexin has been shown to be effective in dealing with diarrhea in various situations. The effects are also seen in clinical trials. In a study published in Govareh Magazine¹, on acute watery diarrhea in Iranian children, found that:

- Mean duration of diarrhea was 33% (2.3 days) lower in the probiotic group and the daily times of watery stool were reduced by 14%. (0.72).
- Nobody in probiotic group suffered by persistent diarrhea or any significant complication.
- Weight decrement after probiotic challenge was significantly less than placebo.

In a separate clinical trial using antibiotic therapy Protexin was shown to have positive results for diarrhea. In the trial at the Children's Medical Center, Pediatrics Center of Excellence, Tehran, where Protexin was tested for H. Pylori eradication², over three quarters of patients had a lower rate of diarrhea during treatment.

In another clinical trial looking at Effects of Synbiotic Supplementation on Breast Milk Levels of IgA, TGF- β 1, and TGF- β 2, with Protexin at Tabriz University of Medical Sciences published in the Journal of Human Lactation it was found that "the incidence of diarrhea in infants decreased significantly in the supplemented group while no significant changes were observed in the placebo group after the experimental period."³

Protexin has been shown to be effective in clinical trials on various types of diarrhea.

CONSTIPATION

Protexin has been shown to be effective in clinical trials on chronic functional constipation.

Constipation can be just as much related to microbial dysbiosis as diarrhea. In a clinical trial, published in the Swiss Medical Weekly, measuring mean stool frequency of soldiers with functional constipation in the Iranian army after the administration of Protexin, the researchers came to the conclusion that: " this specific commercial product seemed to be effective in increasing stool frequency and improving consistency in this sample of males with functional constipation."⁴

In another clinical trial at the Children's Medical Center, Pediatrics Center of Excellence, Tehran, published in the Iranian Journal of Pediatrics, Protexin increased the number of bowel movements per week and the researchers concluded: "This study showed that synbiotics have positive effects on symptoms of childhood constipation without any side effects."⁵

Frequency and consistency of defecation were also seen to improve significantly in a separate clinical trial, published in the International Journal of Pediatrics, which found that Protexin "had a positive role in increasing the frequency and improving the consistency at the end of 4th week."⁶

INFANT COLIC

Protexin can be considered as a supplement to aid the symptoms of infant colic. In a clinical study published in the Australian Journal of Paediatrics and Child Health, Mashhad University Medical School researchers found that "treatment success was significantly higher in synbiotic group at day 7 and at day 30. There was no complication related to the Protexin synbiotic use. The researchers concluded "This synbiotic significantly improved colic symptoms in comparison with placebo."⁷

Published in the Australian Journal of Paediatrics and Child Health, this clinical trial with Protexin "significantly improved colic symptoms."

COMMON COLD & INFLUENZA

In helping to modulate the immune system, Protexin could be a useful aid during the cold and flu season.

Protexin can also have an immunity pathway in the protection against viral infections in cold and flu; in clinical trials it has been seen to have a positive effect in immune system factors. In a study on male athletes, it was found that Protexin consumption "following exhaustive exercise can cause increase in factors of lymphocyte, monocyte, and geranocyte, and therefore it seems that probiotics play a role in the development of immune system."⁸

In the trial on the Effects of Synbiotic Supplementation on Breast Milk Levels of IgA, TGF- β 1, and TGF- β 2, an increase of IgA in breast milk was reported and TGF- β 2 increase of over 41% by giving Protexin to lactating mothers.³

A systematic review and meta-analysis in the British Journal of Nutrition in 2014, revealed significantly fewer numbers of days of illness per person, shorter illness episodes by almost a day and fewer numbers of days absent from day care/school/work. Another systematic review in 2015 on Probiotics the prevention of pediatric upper respiratory tract infections, saw at least one beneficial effect of prophylactic probiotic in the majority of RCTs.

WITH ANTIBIOTICS

In clinical trials Protexin has been shown to be effective in helping compliance with antibiotic therapy.

Antibiotic therapy creates significant dysbiosis of the gut microbiota and it is important that the microbial community return to a better state as quickly as possible. This is especially the case with strong antibiotic therapy such as in the treatment of H. Pylori. In a clinical study on the use of Protexin alongside the treatment of H. Pylori with omeprazole, amoxicillin and furazolidon at the Children's Medical Center, Pediatrics Center of Excellence, Tehran, the researchers recommended Protexin as an adjuvant therapy "in order to reduce the frequency of antibiotic induced side-effects during the treatment with antibiotics".²

In 2016, a clinical trial, "The Effect of Probiotic Plus Prebiotic Supplementation on the Tolerance and Efficacy of Helicobacter Pylori Eradication Quadruple Therapy: a Randomized Prospective Double Blind Controlled Trial" was published in the Middle Eastern Journal of Digestive Diseases, where Protexin Balance was administered to patients from Rasht and Anzali in Iran, two capsules before lunch, starting three days before the quadruple antibiotic therapy of amoxicillin, clathithromycin and omeprazole. The researchers reported that "The eradication rate was significantly better in the synbiotic group by intention-to-treat analysis. [Protexin] could improve the eradication by augmenting the treatment tolerance and compliance."⁹

PROTEXIN USAGE

IRRITABLE BOWEL SYNDROME, INFLAMMATORY BOWEL DISEASE

Probiotics in general are now a focus for use by patients with chronic conditions and diseases of the digestive system.

Certainly in the wider literature probiotics are considered for use in patients with ulcerative colitis, where the intestinal microbiota is said to be one of the key players in the etiology of the disease.

In IBS, there is also evidence the probiotics in general can have a positive effect on patients with IBS. A systematic review in 2015, covering some 1793 patients found that probiotics reduce pain and symptom severity scores. The results demonstrate the beneficial effects of probiotics in IBS patients in comparison with placebo.

The research on probiotics indicates that they can be effective in IBS, ulcerative colitis.

NON-ALCOHOLIC STEATOHEPATITIS (NASH) / NON-ALCOHOLIC FATTY LIVER DISEASE (NAFLD) / METABOLIC SYNDROME]

In clinical trials, Protexin has been shown to be effective in the treatment and management of metabolic disorders.

The most significant work carried out to date using Protexin with NAFLD and metabolic syndrome has been carried out by the team at the Digestive Diseases Research Institute at the Tehran University of Medical Sciences. Published in both the American Journal of Clinical Nutrition and the British Journal of Nutrition, the researchers stated that over 28 weeks, "Synbiotic [Protexin] supplementation in addition to lifestyle modification is superior to lifestyle modification alone for the treatment of NAFLD, at least partially through attenuation of inflammatory markers in the body." and that "The present results indicate that synbiotic supplementation increases the efficacy of diet therapy in the management of the metabolic syndrome and insulin resistance."¹⁰

A clinical trial carried out at the Esfahan University of Medical Sciences, and published in the International Journal of Preventative Medicine, to investigate the effect of a Protexin and Metformin on Liver Aminotransferases in Non-alcoholic Steatohepatitis found that "Probiotic combination with Metformin improves liver aminotransferases better than metformin alone in patients with NASH."¹¹

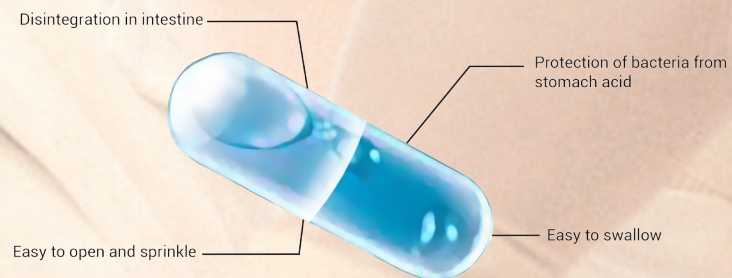
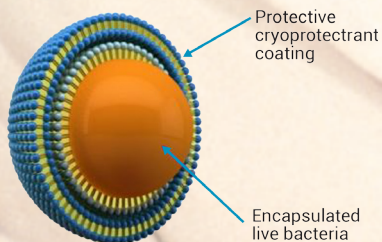
In a separate clinical trial at the Shahid Beheshti University of Medical Sciences entitled "The effects of synbiotic therapy on anthropomorphic measures, body composition and blood pressure in patients with metabolic syndrome: a triple blind RCT", published in the Medical Journal of the Islamic Republic in 2015, over a period of three months, the researchers found that "Synbiotic [Protexin] supplement with the weight loss diet had synergistic effects on improvement in systolic blood pressure and anthropomorphic measurements. Based on the findings, synbiotics can postpone the plateau phase of weight loss and it may prevent resistance to further weight loss."¹²

PROTEXIN KEY FACTS

- No need for refrigeration
- Stability guaranteed for two years at room temperature
- High efficacy shown in independent, internationally published clinical trials on Protexin
- Strains exclusive to Protexin
- Strains with high acid stability, pathogen inhibition and hydrophobicity
- Made in England, with 25 years experience
- GMP from the UK Medicines and Health products Regulatory Agency (MHRA)
- Multi-species, multi-strain synbiotic

ADVANCED MANUFACTURING

From microencapsulation to lyophilisation, Protexin is made using the most advanced techniques and materials available. Progressive coating and capsule technology help bacteria travel past the stomach acid and reach the intestine and sites of action.



PRODUCT COMPOSITION AND DETAILS

Lactobacillus casei **PXN 37**
 Lactobacillus rhamnosus **PXN 54**
 Lactobacillus acidophilus **PXN 35**
 Lactobacillus bulgaricus **PXN 39**
 Bifidobacterium breve **PXN 25**
 Bifidobacterium longum **PXN 30**
 Streptococcus thermophilus **PXN 66**
 + Fructooligosaccharide (FOS)

- No contraindications and no risk of overdose
- Vegetarian, halal
- Suitable for Coeliacs and those with lactose intolerance
- Easy for taking on travel

RESTORE

For babies, toddlers and young children



- Cfu: 1×10^9
- 16 Sachets x 1g
- Dosage guide: 1 sachet per day. Vary depending on condition.
- Includes child specific strain *Bifidobacterium infantis*
- Easily dissolved in water, milk or juice, can also be added to food (not hot)
- No adverse taste or odour

BALANCE

For children, teenagers and adults



- Cfu 1×10^8
- 60 capsules x 250mg
- Dosage guide: 1-2 capsules: once or twice daily with food
- Easy to swallow capsules
- Take with food

BALANCE+

With added vitamins



- Cfu: 1×10^8
- + vitamins A, C, E
- 60 capsules x 250mg
- Dosage guide: 1-2 capsules: once or twice daily with food
- Easy to swallow capsules
- Take with food

PROTECT

With added garlic extract



- Cfu: 1×10^9
- + garlic extract
- 60 capsules x 250mg
- Dosage guide: 1-2 capsules: once or twice daily with food
- Easy to swallow capsules
- Take with food



Modern environments can carry a high bacterial load. From youngsters to the elderly, gastrointestinal and immune problems are increasing, illnesses such as diabetes, obesity and metabolic disorders are now linked to health of the gut bacteria. In choosing the right probiotic, health practitioners need to consider that:

"... claims of efficacy should be target specific and should be made only for products that have been found efficacious in carefully designed studies."

"These studies illustrate that one cannot presume that different commercial products will perform in the same manner and that an evidence-based approach to product selection is the best approach."

"There is a tendency to believe that some extrapolation of results could be possible for microorganisms of the same species, and this is especially done by some companies selling products that were not studied and using studies performed with different strains. ...

... related bacterial strains can differ significantly in their genotype, phenotype, and properties.

The implication of this strain specificity are that:

- for commercial products, documentation of health effects must be conducted on the specific strain contained in the product
- one should avoid any extrapolation of positive or negative effects between probiotic strains; ...
- one should not call a probiotic a strain that has not been studied just on the basis that it is taxonomically related to a well-proven probiotic strain."

Marteau P. Evidence of probiotic strain specificity makes extrapolation of results impossible from a strain to another, even from the same species. Annals of gastroenterology & Hepatology 2011.

Studies carried out on Protexin are completely independent and placebo-controlled randomised double or triple blind trials.

CLINICAL TRIALS ON PROTEXIN IN IRAN

Below are a selection of clinical trials on Protexin in Iran:

1. Allahverdi B, Ghorbani Vaghei A, Miri M, Foroughi S, Delfan B. 2014. A randomized clinical trial with a multi strain probiotic product in acute watery diarrhoea in Iranian children. *Govaresh, Scientific Journal of the Association of Gastroenterology and Hepatology*. Autumn;19
2. Khodadad A, Farahmand F, Najafi M, Shoaran M. 2012. Probiotics for the Treatment Of Pediatric *Helicobacter Pylori* Infection: A Randomised Double Blind Clinical Trial. *Iranian Journal of Pediatrics*. Feb;23(1):79-84
3. Nikniaz L, Ostadrahimi A, Mahdavi R, Hejazi M, Hosseini Salekdeh GH. 2013. Effects of Synbiotic Supplementation on Breast Milk Levels of IgA, TGF- β 1, and TGF- β 2. *Journal of Human Lactation*. Nov;29(4):591-6
4. Fateh R, Iravani SH, Frootan M, Rasouli M, Saadat S. 2011. Synbiotic Preparation in Men Suffering from Functional Constipation: A Randomised Controlled Trial. *Swiss Medical Weekly*. Jul;141
5. Khodadad A, Sabbaghian M. 2010. Role of a Synbiotic supplement in the Treatment of Childhood Constipation: A Double-Blind Randomised Placebo Controlled Trial. *Iran J Pediatric*. Nov;20(4):387-392
6. Sadeghzadeh M, Rabieefar A, Khoshnevisasl P, Eftekhari K. 2014. The Effect of Probiotics on Childhood Constipation: A Randomised Controlled Double Blind Clinical Trial. *International Journal of Pediatrics*.
7. Ahanchian H, Kianifar H. 2014. Synbiotic in the Management of Infantile Colic: A Randomised Controlled Trial. *Australian Journal of Pediatrics and Child Health*. Oct;50(10):801-5
8. M. Aghaee, 2014. Effect of Probiotic Supplement on Immune Response in Male Athletes: A Randomized Clinical Trail. *Ghom University of Medical Science/ Qom University of Medical Sciences Journal*.
9. Shafaghi A, Pourkazemi A, Khosravani M, Fakhrie Asl S, Amirimaafi A, Atrkar roshan Z, Abas pourrahimabad J. 2016. *Middle East Journal of Digestive Diseases*. 8(3):179-188
10. Eslamparast T, Poustchi H, Zamani F, Sharafkhah M, Malekzadeh R, Hekmatdoost A. 2014. Synbiotic Supplementation in Non-alcoholic Fatty Liver Disease A Randomised, Double-Blind, Placebo-Controlled Pilot Study. *American Journal of Clinical Nutrition*. Jan;99(3):535-42
11. Shavakhi A, Minakari M, Firouzian H, Assali R, Hekmatdoost A, Ferns G. 2013. Effect of a Probiotic and Metformin on Liver Aminotransferases in Non-Alcoholic Steatohepatitis: A Double Blind Randomised Clinical Trial. *International Journal of Preventive Medicine*. May;4(5):531-537
12. Rabiei S, Shakerhosseini R, Saadat N. 2015. The effects of symbiotic therapy on anthropometric measures, body composition and blood pressure in patient with metabolic syndrome: a triple blind RCT. *Medical Journal of the Islamic Republic of Iran*. May;29



ABREVIATED PRESCRIBING INFORMATION:

Composition: See product composition and details chart. Indications: Prophylactic and restorative effects for the maintenance of a healthy gastrointestinal and immune system. Used in diarrhea, constipation, IBS, Colitis, Acute Respiratory Tract Infection, in conjunction with antibiotic therapy. **Dosage and administration:** See product composition and details chart **Safety and Side Effects :** The strains used in Protexin have been approved by the FDA as GRAS. A small number of patients may experience bloating. In these cases patients can resume taking Protexin and the symptoms will subside. In cases of acute illness and where long term prescription only medicines are used patients should take the supplements under the monitoring of their physician. No pathogenic or virulence properties have been found for lactobacilli, bifidobacteria or lactococci [FAO/WHO, 2001; Aguirre and Collins, 1993] **Warnings and precautions :** Protexin products should not be used in immunocompromised patients and those with Short Bowel Syndrome. **Children under six months:** The product is safe to use in children under 6 months and there is a long history of safe use in that age group. Children at risk would be those who are immunocompromised, including ill preterm neonates, and/or children who have intravenous catheters or other indwelling medical devices. In children under six months Protexin should be used with advice from and under monitoring of the physician. **Pregnant/ Lactating mothers :** Protexin supplements and Protexin contain naturally occurring beneficial microorganisms which have previously shown to be safe to take during pregnancy. However, we would generally recommend that administration is under the monitoring of the physician. **Allergen declaration :** Protexin probiotic supplements contain traces of soya and traces of milk products at a level which will not affect lactose intolerance sufferers. **Interaction with other drugs :** The use of Protexin has no adverse interaction with other medicines. **Other information:** Shelf life : 2 years at *25 C. Does not need refrigeration. **Pack sizes :** See product composition and details chart



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